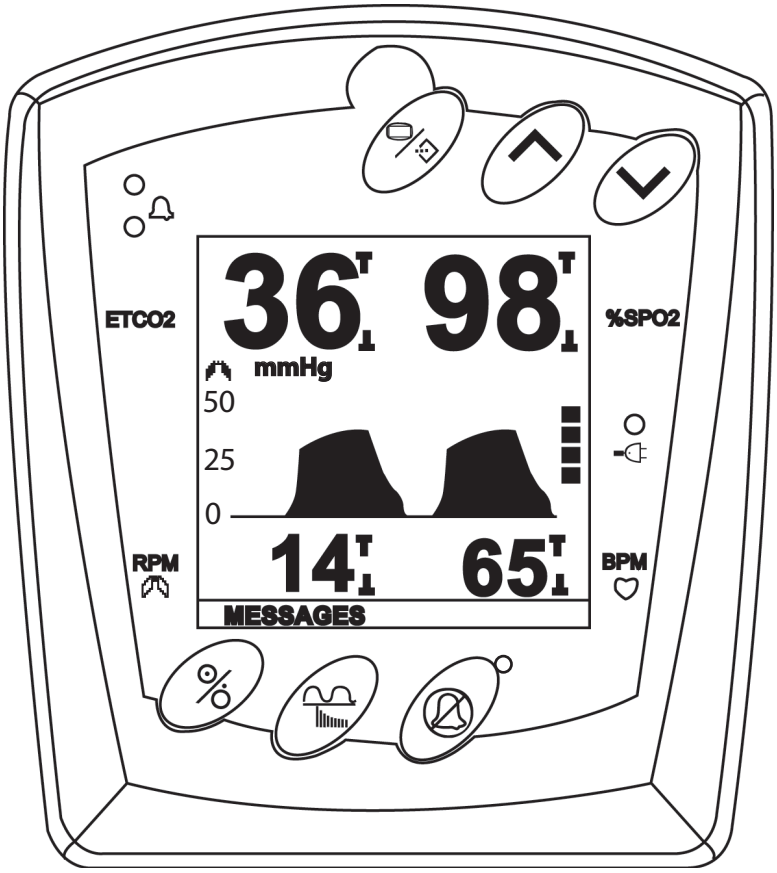
BCI™

Capnograph

Operation Manual



en English
Catalog Number 1894
Version 11, May 2008
© 2008 Smiths Medical family of companies. All rights reserved.

smiths medical

Table of Contents

Warranty and Service Information vii
Proprietary Notice vii
Warranty vii
Limited Warranty vii
Disclaimer of Warranties vii
Conditions of Warranty vii
Limitation of Remedies vii
Warranty Procedure viii
CE Notice viii
Chapter 1: Introduction 1-1
About this manual 1-1
Definition of Symbols 1-1
Warnings, Cautions, and Notes 1-2
General Warnings 1-2
Capnograph Warnings 1-4
Oximeter Warnings 1-4
General Cautions 1-5
Capnograph Cautions 1-6
Notes 1-6
Capnograph Notes 1-6
Oximeter Notes 1-6
Chapter 2: Intended Use and Monitor Features 2-1
Intended use 2-1
Description 2-1
Front Panel 2-2
Display 2-2
Keys 2-3
Backlighting 2-4
Adjusting the Display Contrast 2-4
Top Panel 2-5
Back Panel 2-5

Chapter 3: Setting Up the Monitor 3-1
Unpacking the Monitor and Checking the Shipment 3-1
Using the External Power Supply or Battery 3-1
Turning High, Medium and Low Priority Alarm Tones On and Off 3-2
Working With Menus 3-2
Menu Structure 3-2
Freezing and Releasing Displayed Waveforms 3-3
Working with System-wide Settings 3-4
Setup/Volume Menu 3-4
Chapter 4: Alarms 4-1
High Priority Alarms 4-1
Medium Priority Alarms 4-2
Low Priority Alarms 4-3
Alarm Limit Indicators ⊥, T 4-3
Working With the Alarm Limits Menu 4-4
Adjusting or Viewing Alarm Limits 4-4
Alarm Tones 4-5
Turning Alarm Tones On and Off 4-5
System Alarm Condition: Low Battery 4-5
Chapter 5: CO_2 Theory of Operation 5-1
Theory of Operation 5-1
Measuring CO_2 5-1
Measuring Respiration Rate 5-1
N_2O Compensation 5-2
Chapter 6: Pneumatics and CO_2 Calibration 6-1
Connecting a Non-Recirculating Scavenging System 6-1
Checking for Leaks 6-1
Calibrating the Capnograph 6-1
Low Calibration 6-2
Low/High Calibration 6-2
Auto-Zero 6-3
Connecting the Patient 6-3
Nasal Cannula for Adults and Pediatrics 6-3
Oral/Nasal Cannula for Adults and Pediatrics 6-4
Ventilator Adapters for Adults and Pediatrics 6-4
Nasal Cannula for Infants 6-4

Chapter 7: CO_2 Monitor and Display Menu 7-1
General Description 7-1
CO_2 Monitor Display 7-1
Capnograph Menu 7-2
Turning Capnograph Monitoring On and Off 7-2
Adjusting Waveform Sweep Time or Scales 7-3
Capnograph Messages 7-3
High and Medium Priority Alarm Messages 7-3
Low Priority Alarm Messages 7-3
Status Message 7-3
Calibration Messages 7-4
Chapter 8: Using the Oximeter Option 8-1
General Description 8-1
Pulse Oximetry Theory of Operation 8-1
Oximeter Display 8-3
Oximeter Menu 8-4
Turning Oximeter Monitoring On and Off 8-4
Adjusting Waveform Sweep Time 8-4
Adjusting the Pulse Beep Volume 8-5
Oximeter Messages 8-5
High Priority Alarm Messages 8-5
Low Priority Alarm Messages 8-5
Messages 8-6
Attaching the Patient - Oximetry 8-6
Choose the Sensor 8-6
Clean or Disinfect the Reusable Sensors 8-7
Check Sensor Integrity 8-7
Attach the Sensor to the Patient 8-7
Finger Sensor for Adult or Pediatric Finger 8-8
Checking the Oximeter's Performance 8-8
Chapter 9: Trends 9-1
Trends Menu 9-2
Chapter 10: Printer Output 10-1
Printer Setup 10-1
Printer Menu 10-2
Printer/Output 10-3
Output Examples 10-5
Patient Data 10-5
Trend Table Data 10-5

Chapter 11: Routine Maintenance 11-1
Charging the Battery 11-1
Cleaning and Disinfecting 11-1
Maintenance Chart 11-2
Long Term Storage 11-2
Chapter 12: Troubleshooting 12-1
Troubleshooting the Occlusion Low Priority Alarm 12-2
Chapter 13: Supplies and Accessories 13-1
Ordering Information 13-2
Chapter 14: Specifications 14-1
Capnograph 14-1
Respiration Rate 14-1
SpO_2 (optional) 14-2
Peripheral Pulse Rate (optional) 14-2
Pulse Strength (optional) 14-2
Alarm Limits Ranges 14-3
Serial Output 14-3
Power 14-4
Physical 14-4
Environment 14-4
Appendix A: Guidance and Manufacturer's Declaration A-1
Guidance and Manufacturer's Declaration A-1
Electromagnetic Emissions - Emissions Test A-1
Electromagnetic Emissions – Immunity A-1
Recommended Separation Distances A-4
Appendix B: Revision History B-1

BCI, Comfort Clip and the Smiths design mark are trademarks of the Smiths Medical family of companies. The symbol ® indicates the trademark is registered in the U.S. Patent and Trademark Office and certain other countries. All other names and marks mentioned are the trade names, trademarks or service marks of their respective owners.

This page is intentionally left blank.

Warranty and Service Information

Proprietary Notice

Information contained in this document is copyrighted by Smiths Medical PM, Inc. and may not be duplicated in full or part by any person without prior written approval of Smiths Medical PM, Inc. Its purpose is to provide the user with adequately detailed documentation to efficiently install, operate, maintain, and order spare parts for the device supplied. All information contained in this document is believed to be current and accurate as of the date of publication or revision, but does not constitute a warranty.

Warranty

Limited Warranty

Smiths Medical PM, Inc. ("Seller") warrants to the original purchaser that the Product, not including accessories, shall be free from defects in material and workmanship under normal use, if used in accordance with its labeling, for two years from the date of shipment to the original purchaser.

Seller warrants to the original purchaser that the reusable oximeter sensors supplied as accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with its labeling, for one year from the date of shipment to the original purchaser (USA only).

Disclaimer of Warranties

THE FOREGOING EXPRESS WARRANTY, AS CONDITIONED AND LIMITED, IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Seller disclaims responsibility of the suitability of the Product for any particular medical treatment or for any medical complications resulting from the use of the Product. This disclaimer is dictated by the many elements which are beyond Seller's control, such as diagnosis of patient, conditions under which the Product may be used, handling of the Product after it leaves Seller's possession, execution of recommended instructions for use and others.

Conditions of Warranty

This warranty is void if the Product has been altered, misused, damaged by neglect or accident, not properly maintained or recharged, or repaired by persons not authorized by Seller. Misuse includes, but is not limited to, use not in compliance with the labeling or use with accessories not manufactured by Seller. This warranty does not cover normal wear and tear and maintenance items.

Limitation of Remedies

The original purchaser's exclusive remedy shall be, at Seller's sole option, the repair or replacement of the Product. **THIS IS THE EXCLUSIVE REMEDY. In no event will Seller's liability arising out of any cause whatsoever (whether such cause is based on contract, negligence, strict liability, tort or otherwise) exceed the price of the Product and in no event shall Seller be responsible for consequential, incidental, or special damages of any kind or nature whatsoever, including but not limited to, lost business, revenues, and profits.**

Warranty Procedure

To obtain warranty service in the USA, you must request a Customer Service Report (CSR) number from Technical Service. Reference the CSR number when returning your Product, freight and insurance prepaid, to:

Smiths Medical PM, Inc.	Phone: (262) 542-3100
N7W22025 Johnson Drive	Fax: (262) 542-0718
Waukesha, WI 53186-1856	Toll Free: (800) 558-2345 (U.S.A. only)

Seller will not be responsible for unauthorized returns or for loss or damage to the Product during the return shipment. The repaired or replaced Product will be shipped, freight prepaid, to Purchaser.

To obtain warranty information outside of the USA, contact your local distributor.

Keep all original packing material, including foam inserts. If you need to ship the device, use only the original packaging material, including inserts. Box and inserts should be in original condition. If original shipping material in good condition is not available, it should be purchased from Smiths Medical PM, Inc.

Damages occurred in transit in other than original shipping containers are the responsibility of the shipper. All costs incurred returning devices for repair are the responsibility of the shipper.

CE Notice

Marking by the symbol CE 0473 indicates compliance of this device to the Medical Device Directive 93/42/EEC.

Authorized Representative (as defined by the Medical Device Directive):

Smiths Medical International Ltd.	Phone: (44) 1923 246434
Colonial Way, Watford, Herts,	Fax: (44) 1923 240273
WD24 4LG, UK	

Australian Representative:

Smiths Medical Australasia Pty. Ltd.	Tel: +61 (0) 7 3340 1300
61 Brandl Street, Eight Mile Plains,	
QLD 4113, Australia	

Chapter 1: Introduction

About this manual

The Clinician's Operation Manual provides installation, operation, and maintenance instructions for the health-care professional trained in monitoring respiratory and cardiovascular activity.

These instructions contain important information for safe use of the product. Read the entire contents of these Instructions For Use, including Warnings and Cautions, before using this monitor. Failure to properly follow warnings, cautions and instructions could result in death or serious injury to the patient.

Definition of Symbols

SYMBOL	DEFINITION
	Type CF equipment
	Attention, see instructions for use.
Rx ONLY	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
	Refer servicing to qualified personnel.
	On/Off
	Waveform/Trend or menu exit
	Alarm Silence
	Menu/Enter
	Up or Down arrows
	Alarm (LED)
	External Power / Battery Eliminator LED
ETCO2	End Tidal Carbon Dioxide
	RPM/Respiration Rate
♥bpm	Beats per minute (pulse rate)
%SPO2	Percent Oxygen Saturation
	Breath indicator
⊤	High Alarm Limit Indicator
⊥	Low Alarm Limit Indicator
	Battery Gauge
	Input Voltage
	Printer Output

SYMBOL	DEFINITION
⎓	Direct Current
	Non AP Device
	Date of Manufacture
IPX1	Drip Proof
SN	Serial Number
REF	Catalog Number
	Do not reuse. One use on one patient.
Collect Separately	**Disposal (EU Countries)** Under the Waste Electrical and Electronic Equipment (WEEE) Directive 2006/96/EC and implementing regulations, all devices and service items within the scope of the Directive purchased new after August 13, 2005 must be sent for recycling when ultimately becoming waste. Devices and items must not be disposed of with general waste. If purchased before that date, they may also be sent for recycling if being replaced on a one-for-one, like-for-like basis (this varies depending on the country). Recycling instructions to customers using Smiths Medical products are published on the internet at: **http://www.smiths-medical.com/recycle**
	Disposal (other countries) When disposing of this device, its batteries or any of its accessories, ensure that any negative impact on the environment is minimized. Contact your local waste disposal service and use local recycling or disposal schemes. Separate any other parts of the equipment where arrangements can be made for their recovery, either by recycling or energy recovery. The main batteries are potentially harmful and will require separate disposal according to manufacturer's instructions or local regulations. **Note: If applicable, EU, national or local regulations concerning waste disposal must take precedence over the above advice.**

Warnings, Cautions, and Notes

KEYWORD	DEFINITION
WARNING	Tells you about something that could hurt the patient or hurt the operator.
CAUTION	Tells you about something that could damage the monitor.
NOTE	Tells you other important information.

General Warnings

WARNING! Do not use this device in the presence of flammable anesthetics.

WARNING! ELECTRICAL SHOCK HAZARD when cover is removed. Do not remove covers. Do not disassemble unit. Unit not user serviceable.
⚠ Refer servicing to qualified personnel.

WARNING! Do not use this device in the presence of magnetic resonance imaging (MR or MRI) equipment.

WARNING! Operation of this device may be adversely affected in the presence of computed tomograph (CT) equipment.

WARNING! Do not plug the monitor into an outlet controlled by a wall switch.

WARNING! This monitor is not for home use.

WARNING! This monitor is not intended for use in Sleep Study environments.

WARNING! This device is intended for use by persons trained in professional health care. The operator must be thoroughly familiar with the information in this manual before using the monitor.

WARNING! This device must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in patient assessment.

WARNING! If the accuracy of any measurement is in question, verify the patient's vital sign(s) by an alternative method and then check the monitor for proper functioning.

WARNING! Any monitor that has been dropped or damaged, should be inspected by qualified service personnel, prior to use, to insure proper operation.

WARNING! Operation of this device may be adversely affected in the presence of conducted transients or strong EM or RF sources, such as electrosurgery and electrocautery equipment, x-rays, and high intensity infrared radiation.

WARNING! When connecting to or communicating with this monitor, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. Accessory equipment connecting to or communicating to the monitor's data interface must be certified according to the respective IEC standards, i.e. IEC 60950 for data processing equipment or IEC 601-1 for electro-medical equipment. All combinations of equipment must be in compliance with IEC 601-1-1 systems requirements.

WARNING! IEC 60950 approved equipment including the MCP8850B printer must be placed outside of the "patient environment". The patient environment is defined as an area 1.5m (4.92 feet) from the patient.

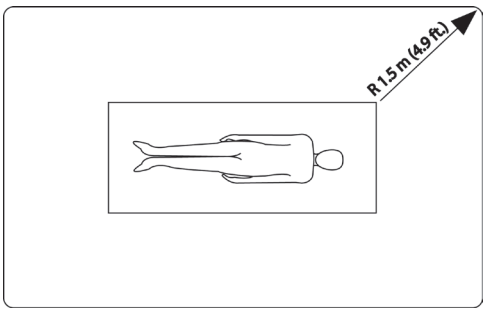


Figure 1.1: Patient Environment

WARNING! In the event that earth ground integrity is lost, the performance of this device and/or other devices nearby may be affected due to excessive RF emissions.

WARNING! Ensure the device's AC rating is correct for the AC voltage at your installation site before using the monitor. The monitor's AC rating is shown on the external power supply. If the rating is not correct, do not use the monitor; contact Smiths Medical PM, Inc. service department for help.

WARNING! Disconnect the AC power supply from the outlet before disconnecting it from the monitor. Leaving the AC power supply connected to an AC power outlet without being connected to the monitor may result in a safety hazard.

WARNING! Do not allow any moisture to touch the AC power supply connectors or a safety hazard may result. Ensure that hands are thoroughly dry before handling the AC power supply.

WARNING! Do not place the monitor in the patient's bed or crib. Do not place the monitor on the floor.

WARNING! Failure to place the monitor away from the patient may allow the patient to turn off, reset, or damage the monitor, possibly resulting in the patient not being monitored. Make sure the patient cannot reach the monitor from their bed or crib.

WARNING! If there is a risk of the AC power supply becoming disconnected from the monitor during use, secure the cord to the monitor several inches from the connection.

WARNING! Patient safety can be compromised by the use of a power supply not be supplied by Smiths Medical PM, Inc. Use only the power supply included with your monitor, or approved by Smiths Medical PM, Inc.

WARNING! The monitor should be operated from its internal power source if the integrity of the protective earth conductor is in doubt.

WARNING! Remove device batteries prior to long term storage.

WARNING! When using the AC battery eliminator, the Capnograph is a class II device with functional earth. This earth connection is for device electromagnetic compatibility and does not provide protection to the patient or user.

WARNING! Do not autoclave, ethylene oxide sterilize, or immerse in liquid. Unplug the external power supply from the monitor before cleaning or disinfecting the monitor.

WARNING! It is the operator's responsibility to set alarm limits appropriately for each individual patient.

Capnograph Warnings

WARNING! Pump motors in the $C0_2$ monitor may adversely affect other medical equipment, e.g. ECG tracings.

WARNING! The presence of anesthetic agents may cause CO_2 readings to deviate beyond specified tolerances.

WARNING! This monitor is not for use as an apnea monitor.

WARNING! The capnography parameter of this monitor is not for use on Neonates.

Oximeter Warnings

WARNING! Failure to carefully route the cable from the sensor to the monitor may allow the patient to become entangled in the cable, possibly resulting in patient strangulation. Route the cable in a way that will prevent the patient from becoming entangled in the cable. If necessary, use tape to secure the cable.

WARNING! Use only SpO_2 sensors supplied with, or specifically intended for use with, this device.

WARNING! Incorrectly applied sensors may give inaccurate readings. Refer to the sensor insert for proper application instructions.

WARNING! Prolonged use or the patient's condition may require changing the SpO_2 sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

WARNING! When attaching SpO_2 sensors with Microfoam® tape, do not stretch the tape or attach the tape too tightly. Tape applied too tightly may cause inaccurate readings and blisters on the patient's skin (lack of skin respiration, not heat, causes the blisters).

WARNING! Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, patent blue V (PBV), and fluorescein, may adversely affect the accuracy of the SpO_2 reading.

WARNING! Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate pulse and SpO_2 readings.

WARNING! Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin (with CO-poisoning) or methemoglobin (with sulfonamide therapy), will adversely affect the accuracy of the SpO_2 measurement.

WARNING! SpO_2 measurements may be adversely affected in the presence of high ambient light. If necessary, shield the sensor area (with a surgical towel, for example).

WARNING! Optical cross-talk can occur when two or more sensors are placed in close proximity. It can be eliminated by covering each site with an opaque material.

WARNING! Remove fingernail polish or false fingernails before applying SpO_2 sensors. Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.

WARNING! Tissue damage may result from overexposure to sensor light during photodynamic therapy with agents such as verteporphin, porfimer sodium and meta-tetrahydroxyphenylchlorin (mTHPC). Change the sensor site at least every hour and observe for signs of tissue damage. More frequent sensor site changes or inspections may be indicated depending upon the photodynamic agent used, agent dose, skin condition, total exposure time or other factors. Use multiple sensor sites.

WARNING! Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO_2 and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates, or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

General Cautions

CAUTION! Do not allow water or any other liquid to spill onto the monitor. Evidence that liquid has been allowed to enter the monitor voids the warranty.

CAUTION! Should the device become wet, wipe off all moisture and allow sufficient time for drying before operating.

CAUTION! Follow local governing ordinances and recycling instructions regarding disposal and recycling of device components.

CAUTION! The monitor contains a 6-hour Lithium Ion (LI+) battery. If the battery fails to hold a charge or otherwise becomes inoperable, the battery should be replaced and the old battery should be disposed of properly. Consult local officials for information about the proper disposal of the Lithium Ion battery. Smiths Medical PM, Inc. cannot dispose of monitor batteries.

CAUTION! Pressing front panel keys with sharp or pointed instruments may permanently damage the keypad. Press front panel keys only with your finger.

CAUTION! Chemicals used in some cleaning agents may cause brittleness of plastic parts. Follow cleaning instructions in this manual.

Capnograph Cautions

CAUTION! Do not use the device without the appropriate filter attached. Use of any other filter will cause degradation in performance, and/or permanently damage the device.

CAUTION! Use of monitor during continuous nebulized medication delivery will result in damage to the monitor (not covered by factory warranty). Disconnect the $ETCO_2$ sample line from the patient circuit or power monitor off during medication delivery.

Notes

NOTE! All user and patient accessible materials are non-toxic.

NOTE! Hazards arising from software errors have been minimized. Hazard analysis was performed to meet EN14971:2000.

NOTE! Each input and output connection of the monitor is electrically isolated.

NOTE! Performance and safety test data are available upon request.

NOTE! To comply with government requirements for patient monitoring, the indefinite high priority alarm, medium priority alarm and low priority alarm tone silence feature may not be available in monitors shipped to your country.

Capnograph Notes

NOTE! InCO_2 is only displayed on the message line, and only if it has exceeded its alarm limit.

NOTE! Capnograph patient attachments, sample lines, and filters are disposable, single-patient use items. Use a new patient attachment, filter and sample line for each new patient.

NOTE! Discard and replace the patient attachment if it becomes occluded. If an air leak is noted, check all patient connections. If the air leak persists, discard and replace the patient attachment.

Oximeter Notes

NOTE! Alarm settings are maintained when power is turned off, except for the following.

NOTE! The low SpO_2 alarm limit minimum test value is 80. If an operator changes the low SpO_2 alarm limit to a value less than 80, and a power down - power up sequence takes place, a minimum value of 85 takes the place of the operator entered value.

Chapter 2: Intended Use and Monitor Features

Intended use

The Capnograph is a low-cost CO_2 monitor with optional oximetry and optional external printer. It may be used in the hospital or clinical environment, and during emergency land transport. It is not intended for use in the home. It is intended to be used in all critical environments, including ventilatory applications, patient ground transport, EMS (Emergency Medical Services) and anesthesia. The capnography parameter provides end tidal CO_2 ($ETCO_2$) inspired CO_2 (in CO_2) and respiration rate measurements on all patients from pediatric to adult. The oximetry option works with all BCI® oximetry sensors, providing $\%SpO_2$ and pulse rate on all patients from pediatric to adult. The Capnograph permits continuous patient monitoring with adjustable alarm limits as well as visual and auditory alarm signals. It is not intended nor designed to be used as an apnea monitor.

Description

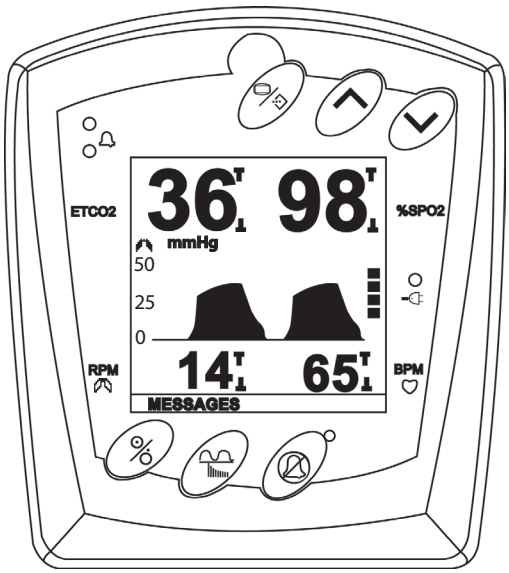


Figure 2.1: Waveform Mode

Parameters

The monitor is a capnograph with optional oximetry monitoring (8401: Capnograph only; 8400: Capnograph and Oximeter). Alarm limits can be set on all monitored parameters.

Capnograph

The monitor performs side-stream capnography and displays End-Tidal CO_2 ($ETCO_2$) and Inspired CO_2 ($inCO_2$) in measurement units of millimeters of mercury (mmHg), kilo pascals (kPa), or percent volume (%), as well as Respiration Rate per minute (RPM). An optical microbench provides the CO_2 measurements. A CO_2 waveform is displayed along with a breath indicator. The user may enable 40% Nitrous Oxide (N_2O) compensation.

Oximeter (optional)

The monitor also supports oximetry, which continuously measures and displays arterial blood oxygen saturation ($\%SpO_2$) and Pulse Rate (BPM). Oximetry includes the display of a plethysmogram and pulse strength bar. The monitor beeps with each pulse beat. The volume of the pulse beep is adjustable. The pitch of the pulse beep varies with the $\%SpO_2$ value. A variety of disposable and reusable sensors are available for monitoring pediatric to adult patients.

Audio

The monitor uses a multi-frequency speaker for beeps and high priority, medium priority, and low priority alarm sounds. Volumes are adjustable.

Serial Output
An infrared serial interface allows serial output of text data to a Martel MCP8850B compatible serial printer. There is no waveform data sent out the serial port.

Power
The Capnograph operates on power from an external power supply or an internal battery, which will allow operation for approximately six hours.

Front Panel

Display

The LCD display has an electroluminescent (EL) back light, and provides continuous, real-time updates of waveforms or measurement trends, all measured values, and alarm messages. The display also shows alarm limit indicators, menus, a pulse strength bar, a breath indicator and the "N_2O compensation enabled" indicator.

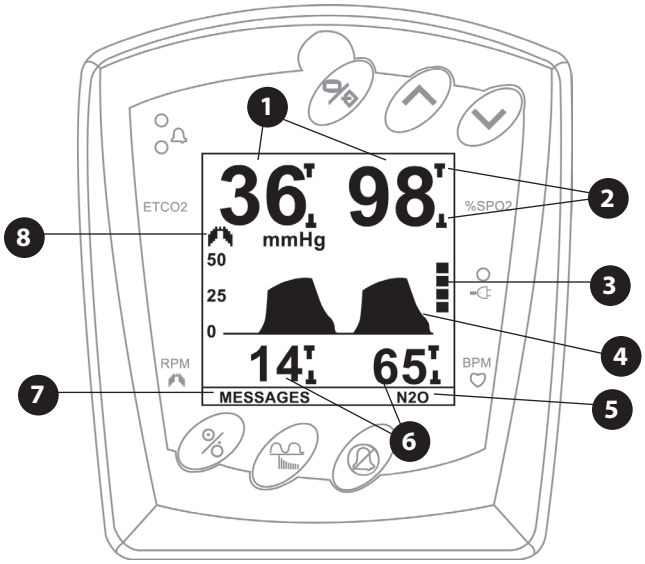


Figure 2.2: Front Panel

1 Main Parameters
The $ETCO_2$ (left side) and optional $\%SpO_2$ (right side) readings are displayed in this area as large digits.

2 Alarm Limit Indicators
Displayed if the corresponding limit is not set to OFF. Indicator blinks if limit is violated. Every set of digits has at least one alarm limit. The top indicator of a pair is for the high limit, the bottom indicator is for the low limit.

3 Pulse Bargraph (oximetry option)
The pulse signal strength is displayed from the oximeter.

4 Waveforms, Trends, Menus
One waveform is displayed here in waveform mode. A trend graph or a menu can be displayed in place of the waveform.

5 N_2O Compensation Indicator or Battery Gauge
The lower right corner of the display is used to display the battery gauge symbol and "N_2O" when N_2O compensation is enabled.

6 Secondary Parameters
The respiration rate (RPM, left side) and optional pulse rate (BPM, right side) are displayed as large digits in meter mode, and medium digits when a waveform, trend graph or menu is displayed.

7 Message Area
Messages for alarms and system information are displayed on this line. If more than one message must be displayed, they alternate once per second.

8 Breath Indicator
This indicator is shown when the C02 parameter is detecting breaths. It is solid during inhalation, and empty (outlined) during exhalation.

Keys

The front panel keys control the monitor's functions. Dedicated keys are provided for turning the monitor on and off, selecting waveforms or trends, silencing alarm tones, and selecting menu options.

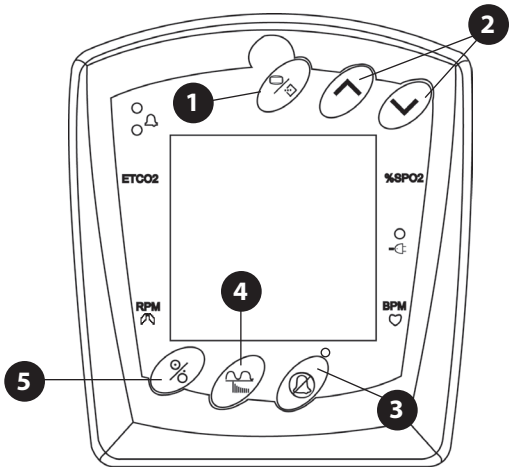


Figure 2.3: Keys

1 MENU/ENTER
Press this key to display the list of menus. While menus are displayed, press to select a menu item or to accept a value that has been adjusted.

2 ∧∨ UP/DOWN ARROWS
If a menu is displayed, press ∧ or ∨ to move among menu items or to adjust the value of a selected item. If a Trend is displayed, the ∧ or ∨ keys cycle between trended parameters. If a menu or trend is not displayed, press the ∧ or ∨ keys to adjust display contrast.

3 ALARM SILENCE
Pressing disables the auditory alarm tones for two minutes (yellow light on this key flashes). Pressing and holding this key for about three seconds disables the alarm tones indefinitely (yellow light on this key is lit and not flashing). Pressing this key momentarily cancels either alarm silence condition. The monitor defaults to two-minute alarm silence at power up.

4 WAVE/TREND
This key controls the waveform area display. Press this key to display the CO_2 waveform, optional oximetry plethysmogram, a trend or meter mode (large parameter values only, no waveforms or trends). Press while menus are displayed for a quick menu exit. The waveform or trend previously displayed will replace the menu.

5 % OFF/ON
Pressing % switches the monitor between ON (monitoring a patient) and OFF. The first press of the OFF key displays a warning indicating all trends will be lost. Pressing % again turns off the monitor.

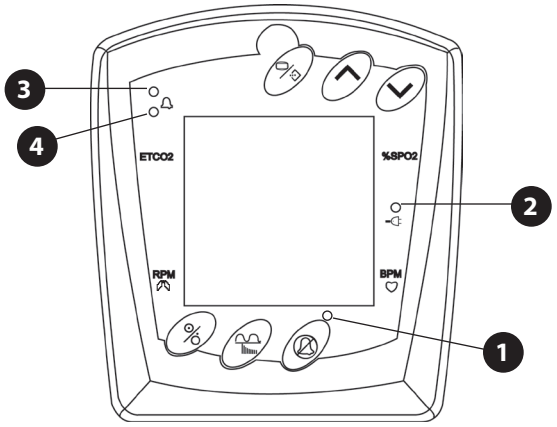


Figure 2.4: LEDs

1 Alarm Silence LED (yellow)
Flashes during two-minute alarm silence. Stays on steadily during indefinite alarm silence.

2 External Power LED (green)
Is on steady while external power is applied. If the battery is used, then this LED is off.

3 Medium and Low Priority Alarm LED (yellow)
This indicator flashes yellow during a MEDIUM PRIORITY ALARM, and is illuminated steadily during a LOW PRIORITY ALARM.

4 High Priority Alarm LED (red)
This HIGH PRIORITY ALARM indicator flashes red during patient alarm.

Backlighting

The display backlight can be turned on for better display visualization or use at night.

To turn the backlight on or off:

1. Press the MENU/ENTER key ( ). Menus replace any waveforms displayed.
2. Press the ARROW keys (^ or v) until the selector arrow points to "Backlight" then press MENU/ENTER ( ).
3. Again press the MENU/ENTER key ( ) to highlight the backlight option. Use the ARROW keys (^ or v) to select "Off" or "On" then press the MENU/ENTER key ( ) to accept that setting.
4. To exit the menu, select the **[EXIT]** menu item.
5. To exit all menus quickly and return to the previous monitoring screen, press the WAVE/TREND key ( ).

Adjusting the Display Contrast

If no trends or menus are displayed, and only the large parameter values are shown, the display contrast can be adjusted.

When the monitor is in "Meter Mode," large parameter values only are displayed. The contrast can be adjusted by using the ARROW keys (^ or v).

Top Panel

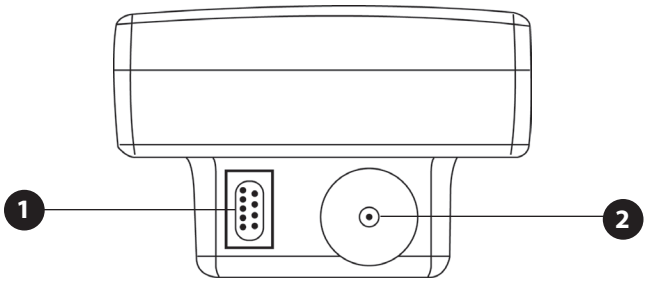


Figure 2.5: Top Panel

1 SpO_2 Connector (optional)

The oximeter sensor patient cable is connected here.

2 Gas Inlet Port

The capnograph moisture filter and sample line are connected here. The patient sample line should never be connected directly to this port. A disposable moisture filter connects to the port, and the sample line connects to the moisture filter.

Back Panel

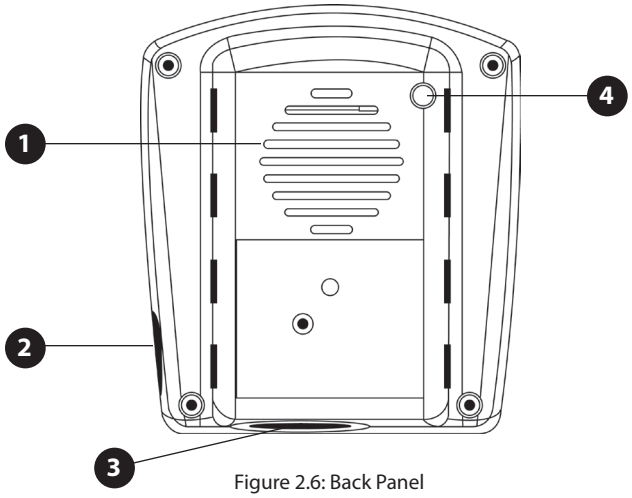


Figure 2.6: Back Panel

1 Speaker Grille

The speaker grille provides speaker output.

2 Serial Output

Serial infrared printing can take place through this port. Use the Martel MCP8850B printer (See *Chapter 13: Supplies and Accessories* for catalog number).

3 Power Input

The external power supply or battery is inserted into this compartment.

8403	Battery Eliminator, AC Power Supply 105-125 V, 60 Hz
8406	Battery Eliminator, AC Power Supply 208-252 V, 50/60 Hz
8407	Battery Eliminator, AC Power Supply 90-110 V, 60 Hz

4 Gas Exhaust Port

A scavenging line may be connected to this port. Gas sampled by the monitor is removed through this port.

This page is intentionally left blank.

Chapter 3: Setting Up the Monitor

Unpacking the Monitor and Checking the Shipment

Carefully remove the monitor and accessories from the shipping carton. Save the packing materials in case the monitor or accessories must be shipped or stored. Compare the packing list with the accessories received to make sure the shipment is complete.

WARNING! Any monitor that has been dropped or damaged, should be inspected by qualified service personnel, prior to use, to insure proper operation.

Using the External Power Supply or Battery

See *Chapter 13: Supplies and Accessories* to verify the use of the proper battery, battery charger, and AC battery eliminator.

Remove the battery from the shipping material. Locate the circular door on the bottom of the monitor. Turn one-quarter turn counter clockwise. Pull and lift the door away from the opening. Guide the battery, metal tabs first, into the compartment. Replace the circular door closing with a one-quarter turn clockwise.

An optional AC power supply/battery eliminator is available. The power supply is shaped similar to the battery with a power cord attached. Locate the circular door on the bottom of the monitor. Turn one-quarter turn counter clockwise. Pull and lift the door away from the opening. Guide the power supply unit, metal tabs first, into the compartment. Secure the power cord into the guide at the opening of compartment. Replace the circular door, closing with a one-quarter turn clockwise.

NOTE! When using the AC battery eliminator, the Capnograph is a class II device with functional earth. This earth connection is for device electromagnetic compatibility and does not provide protection to the patient or user.

WARNING! Disconnect the AC power supply from the outlet before disconnecting it from the monitor. Leaving the AC power supply connected to an AC power outlet without being connected to the monitor may result in a safety hazard.

WARNING! Do not allow any moisture to touch the AC power supply connectors or a safety hazard may result. Ensure that hands are thoroughly dry before handling the AC power supply.

WARNING! Do not place the monitor in the patient's bed or crib. Do not place the monitor on the floor.

WARNING! Failure to place the monitor away from the patient may allow the patient to turn off, reset, or damage the monitor, possibly resulting in the patient not being monitored. Make sure the patient cannot reach the monitor from their bed or crib.

WARNING! If there is a risk of the AC power supply becoming disconnected from the monitor during use, secure the cord to the monitor several inches from the connection.

Turning High, Medium and Low Priority Alarm Tones On and Off

When the monitor is turned on, the high, medium, and low priority alarm tones are silenced for two minutes. The SILENCED indicator, which is on the ALARM SILENCE (🔕) key, flashes during the two minute alarm silence.

To silence the high, medium, and low priority alarm tones indefinitely: Press and hold ALARM SILENCE (🔕)for about three seconds; the SILENCED indicator lights steady.

NOTE! To comply with government requirements for patient monitoring, the indefinite high priority alarm, medium priority alarm and low priority alarm tone silence feature may not be available in monitors shipped to your country.

To silence the high, medium and low priority alarm tones for two minutes: Momentarily press ALARM SILENCE 🔕; the SILENCED indicator flashes. If tones are already silenced, press ALARM SILENCE (🔕) twice (the first press cancels alarm silenced; the second press silences the alarms for two minutes).

To cancel either two minute or indefinite alarm silence and enable high, medium, and low priority alarm tones: Momentarily press ALARM SILENCE (🔕); the SILENCED indicator turns off.

Working With Menus

Menu Structure

Freeze Wave

Backlight
- Display Backlight: ON/OFF

Alarm Limits
- Set ETCO2 High and Low Alarms
- Set Resp Rate High and Low Alarms
- Set inCO2 High Alarm
- Set SpO2 High and Low Alarms*
- Set Pulse Rate High and Low Alarms*

Volume
- Adjust Alarm Volume (1-15)
- Adjust Pulse Volume (1-15)*

Capnograph
- Low CO2 Calibration
- Low/High CO2 Calibration
- Select CO2 Waveform Scale
- Select CO2 Waveform Sweep Speed
- Select CO2 Units (mmHg, kPa, %)
- Enable/Disable 40% N20 Compensation
- Disable/Enable Capnograph Monitor

Oximeter
- Disable/Enable Oximeter Function
- Select Pleth Waveform Sweep Speed

Trends
- Select Display Time Span
- Select Trend Display Scales for Each Parameter
- Clear Trend Memory

Printer
- Start/Stop Printer Output
- Select Data Format (Patient Data or Trend Tables)
- Select Print Interval or Trend Time Span

** If oximetry is installed.*

The operator chooses various monitor settings through menus that appear in the waveform area. The MENU/ENTER (⏻/◈) key and ARROW (∧ or ∨) keys are used to select menu items and change settings.

1. To show the Main menu: Press the MENU/ENTER (⏻/◈) key. Menus replace any waveforms displayed.

2. To select a menu item: Press the ARROW (∧ or ∨) keys until the selector arrow points to the desired item, then press MENU/ENTER (⏻/◈). This will either take you to a new menu, start a function such as calibration, or allow the selected item to be adjusted.

3. To change a setting for a selected menu item: After pressing MENU/ENTER (⏻/◈) as in step 2, the item that can be changed will be highlighted. Use the ARROW (∧ or ∨) keys to select the desired setting, then press MENU/ENTER (⏻/◈) to accept that setting.

4. To exit the current menu: Select the **[EXIT]** menu item.

5. To exit all menus quickly and return to the previous monitoring screen: Press WAVE/TREND (〰).

NOTE! If menus are shown and you do not press a key for 20 seconds, the waveform display will return, and any current menu selections will be accepted.

Freezing and Releasing Displayed Waveforms

Displayed waveforms, except trends, can be frozen and released quickly. To freeze or release waveforms, press: MENU/ENTER (⏻/◈) twice.

- The first key press displays the Main Menu.
- The second key press selects the first item in the Main Menu, which is "Freeze Wave" This automatically exits the Main Menu to the waveform screen to show the results.
- If waveforms are already frozen, "Freeze Wave" allows them to update again.

NOTE! While waveforms are frozen, the message "Waves Frozen" is shown in the message area at the bottom of the display (subject to message priority).

NOTE! Trends are not affected by the waveform freeze feature. Trends continue to be collected while the waveforms are frozen.

NOTE! Displayed numeric values are not affected by the waveform freeze feature. The numeric values continue to be updated and displayed while the displayed waveforms are frozen.

Working with System-wide Settings

This section describes working with system-wide settings using the **Volume** menu. For information on the parameter menus, refer to the chapter of the manual that describes the parameter.

Setup/Volume Menu

The following system-wide settings are viewed and/or adjusted from the Volume menu.

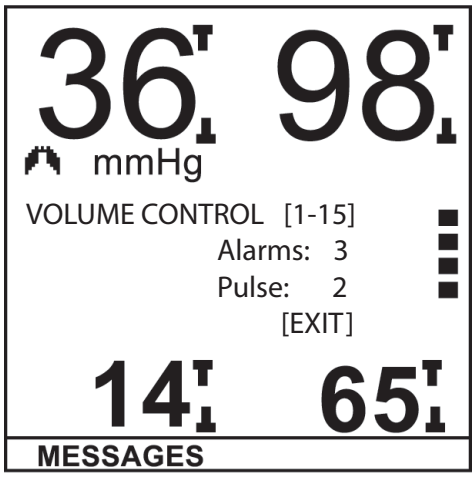


Figure 3.1: Setup Menu

Alarm Volume

Indicates the Alarm volume. Allows the volume to be adjusted in the range of 1 to 15. Alarm volume can not be turned off.

Pulse Volume (oximetry option)

Indicates the pulse beep volume, adjustable in the range of 1 to 15 and OFF.

Chapter 4: Alarms

High Priority Alarms

A *high priority alarm* warns you when a patient's measurement matches or exceeds the high or low alarm limit for that measurement. For example, if the low SpO_2 alarm limit is set to 85, and the patient's measured $\%SpO_2$ is 75, an alarm is triggered.

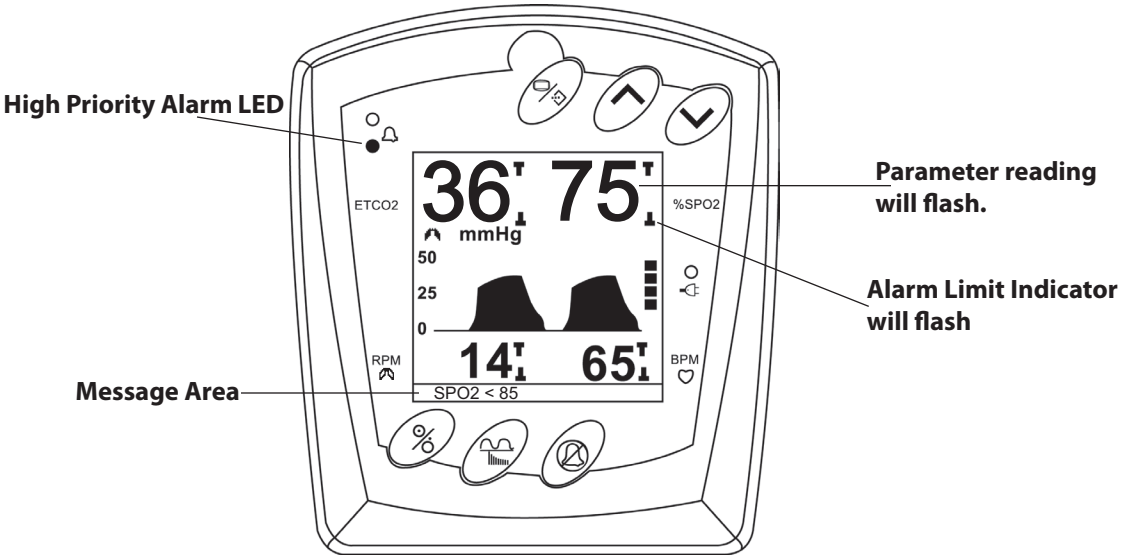


Figure 4.1: High Priority Alarm Example

During a high priority alarm:

- The HIGH PRIORITY ALARM LED flashes red.
- The digits for the violated alarm limit flash.
- The alarm limit indicator for the violated parameter flashes.
- A message is displayed. Multiple messages alternate once per second.
- The high priority alarm tone sounds (if not silenced).

NOTE: The high priority alarm actions occur for each violated alarm, even if more than one alarm is violated at the same time.

CAUTION! It is the operator's responsibility to set alarm limits appropriately for each individual patient.

Medium Priority Alarms

A *medium priority alarm* warns you when a patient's $ETCO_2$ or respiration rate measurement matches or exceeds the high or low alarm limit for that measurement during the first 2 minutes after power up. After 2 minutes, the medium priority alarm will become a high priority alarm, if the alarm limits are still exceeded.

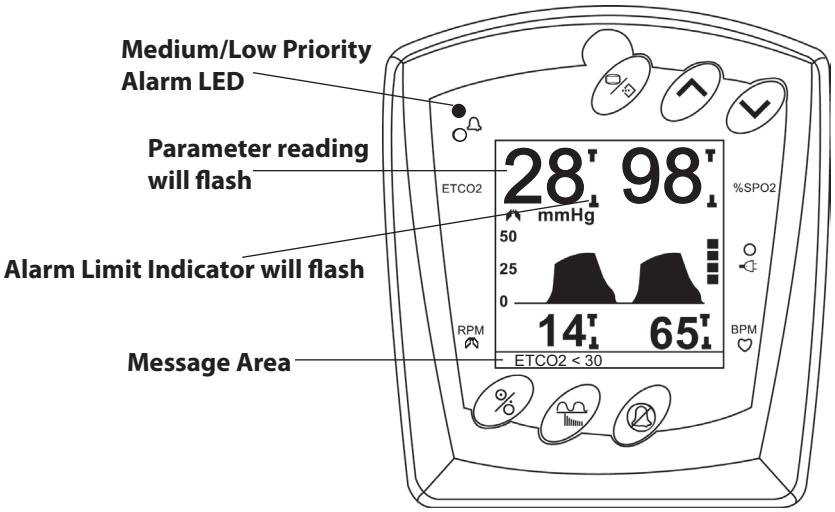


Figure 5.2: Medium Priority Alarm Example

During a medium priority alarm:

- The MEDIUM/LOW PRIORITY ALARM LED flashes yellow.
- The digits for the violated parameter flash.
- The alarm limit indicator for the violated parameter flashes.
- A message is displayed. Multiple messages alternate once per second.
- The medium priority alarm tone sounds (if not silenced and if no high priority alarms are active).

Low Priority Alarms

A low priority alarm warns you about a condition that prevents the monitor from taking a measurement. For example, if oximetry is installed, and the SpO_2 sensor is not connected to the monitor, the monitor can-not measure the patient's pulse rate or SpO_2 value. In this case, a low priority alarm is triggered.

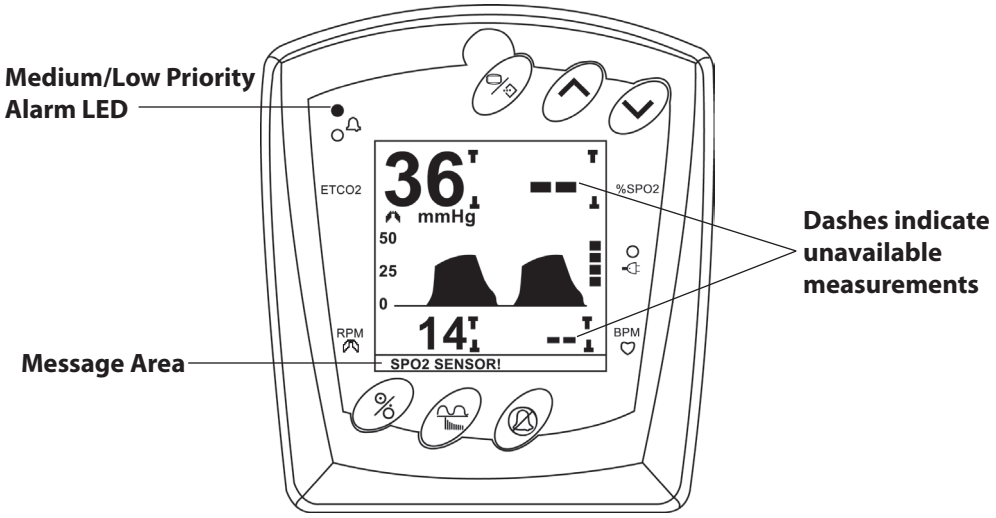


Figure 4.3: Low Priority Alarm Example

During a low priority alarm:

- The MEDIUM/LOW PRIORITY ALARM LED is steady yellow, if no medium priority alarms are active.
- A message is displayed. Multiple messages alternate once per second.
- The low priority alarm tone sounds (if not silenced and if no high or medium priority alarms are active).
- Dashes indicate the measurement is unavailable.

Alarm Limit Indicators ⊥ , T

The upper indicator represents the high alarm limit; the lower indicator represents the low alarm limit. Each indicator shows three conditions:

ALARM INDICATOR	ALARM LIMIT CONDITION
Not Displayed	The alarm limit is set to OFF
On Steady	The alarm limit is set and is not violated.
On and Flashing	The alarm limit is violated.

Working With the Alarm Limits Menu

This section describes working with alarms using the Alarm Limits menu. For information on the parameter menus, refer to the chapter of the manual that describes the parameter.

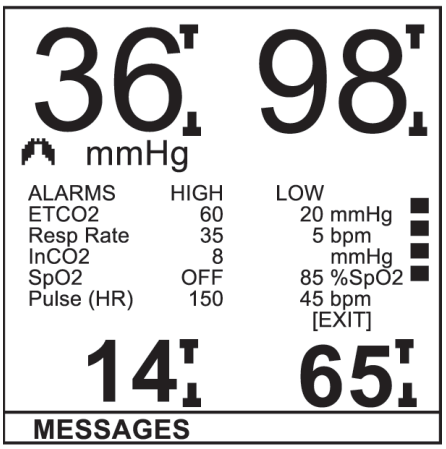


Figure 4.4: Alarm Limits Menu

HIGH and LOW
Indicates the high and low alarm limit for each measurement. Allows the alarm limits to be adjusted.

[EXIT]
Exits the Alarm Limits menu.

Adjusting or Viewing Alarm Limits

1. From the Main menu, select the **Alarm Limits** item.
2. Using the ARROW (^ or v) keys, select the alarm limit to be changed under the **HIGH** or **LOW** column.
3. Press the MENU/ENTER ( ) key to highlight the value. Use the ARROW (^ or v) keys to adjust the value. Press the MENU/ENTER ( ) key to set the value.
4. Select **[EXIT]** or press the WAVE/TREND ( ) key to exit menu.

NOTE! High and medium priority alarms can be tested while the monitor is in use by setting the alarm limits such that the measured parameter reading is outside the alarm limits. Be sure to restore alarm limits to the required settings after testing.

NOTE! (For optional oximeter) Low priority alarms can be tested by disconnecting the oximetry sensor. Be sure to connect the sensor after testing.

NOTE! Alarm limit settings are retained during power cycles, except for the following.

NOTE! (For optional oximeter) If either the high or low SpO_2 limit is set below 80% when the device is powered down, the limit will reset to 85% or higher, when power is returned to the device.

Alarm Tones

The high priority alarm tone is a series of two bursts of five beeps (beep, beep, beep, pause, beep, beep) repeated twice every 10 seconds. The medium priority alarm tone is a series of 3 beeps repeated every 20 seconds. The low priority alarm tone is a series of 2 beeps repeated every 20 seconds.

- The alarm volume can be adjusted in the **Setup/Volume** menu.
- The alarm volume can not be set to OFF.
- All alarm tones except the Low Battery signal can be silenced.

Turning Alarm Tones On and Off

When the monitor is turned on, the alarm tones are silenced for two minutes. The SILENCED indicator on the ALARM SILENCE (🔕) key flashes during the two minute time-out.

- To silence the alarm tones indefinitely: Press and hold ALARM SILENCE (🔕) for about three seconds; the SILENCED indicator lights steady.

NOTE! To comply with government requirements for patient monitoring, the indefinite alarm and low priority alarm tone silence feature may not be avail-able in monitors shipped to your country.

- To silence the alarm tones for two minutes: Momentarily press ALARM SILENCE (🔕); the SILENCED indicator flashes. If tones are already silenced, press ALARM SILENCE (🔕) twice (the first press cancels alarm silenced; the second press silences the alarms for two minutes).
- To cancel either two minute or indefinite alarm silence and enable alarm tones: Momentarily press ALARM SILENCE (🔕); the SILENCED indicator turns off.

System Alarm Condition: Low Battery

A low battery condition will be detected when the battery has about 30 minutes remaining. As soon as the condition is detected:

- The message **L0W BATTERY** is displayed in the message line at the bottom of the display. It alternates with other messages once per second.
- This message remains displayed until the monitor is connected to power.
- Unique informational signal tone, a burst of 5 beeps at mid-volume, sounds as soon as the low battery condition is detected, and every 30 seconds thereafter while the condition persists.
- The volume of the low battery signal tone is not adjustable.
- The low battery signal tone cannot be disabled by the ALARM SILENCE (🔕) key.
- When the battery has approximately 5 minutes remaining, the low battery condition switches to a medium priority alarm. The MEDIUM/LOW PRIORITY ALARM LED is illuminated. The medium priority alarm tone sounds, if not silenced, and if no high priority alarms are active.

This page is intentionally left blank.

Chapter 5: CO_2 Theory of Operation

Theory of Operation

Measuring CO_2

The device draws a sample of gas through the sample chamber. A light source shines infrared (IR) light through an optical bandpass filter and then through the sample chamber. An IR detector responds to the amount of IR light that passes through the sample chamber.

Because CO_2 absorbs IR light at a specific wavelength, the amount of light passing through the sample chamber varies according to the concentration of CO_2 in the sample chamber. When there is a high concentration of CO_2 in the sample chamber, the detector senses a smaller amount of light than when there is a low concentration of CO_2.

The device computes the partial pressure of CO_2 STPD (standard temperature, pressure, dry) based on measured levels of IR light intensity. The $ETCO_2$ measurement is shown as an average of 4 breaths.

CAUTION! Pump motors in the CO_2 monitor may adversely affect other medical equipment, e.g. ECG tracings.

Measuring Respiration Rate

The device uses the continuous CO_2 waveform to detect each breath cycle. It uses an adaptive algorithm to recognize each breath in the waveform, even in the presence of an elevated baseline (rebreathing) and higher frequencies in the CO_2 waveform (cardiogenic oscillations).

The device computes respiration rate (RPM) from the total number of seconds for the last four breaths according to this formula:

$$\text{RPM} = \frac{60 \text{ seconds x breaths}}{\text{Number of seconds for 4 breaths}}$$

N_2O Compensation

The interfering effect of N_2O results in inaccurate CO_2 readings; however, the device has the ability to compensate for this.

With the N_2O compensation ENABLED, the device adjusts the CO_2 reading by an algorithm that assumes the concentration of N_2O is 40% and compensates accordingly. If N_2O compensation is enabled and the concentration of N_2O is not 40%, the displayed value must be adjusted by the following equation to get the actual CO_2 concentration:

$$\text{Actual CO2} = \frac{\text{CO2 Reading x 1.0625}}{1 + \left(\frac{\text{0.0625 x N2O\%}}{40\%} \right)}$$

With the N_2O compensation DISABLED, the device adjusts the CO_2 reading by an algorithm that assumes the concentration of N_2O is 0%. If N_2O compensation is disabled and the concentration of N_2O is not 0%, the displayed value must be adjusted by the following equation to get the actual CO_2 concentration:

$$\text{Actual CO2} = \frac{\text{CO2 Reading}}{1 + \left(\frac{\text{0.0625 x N2O\%}}{40\%} \right)}$$

NOTE! The presence of other anesthetic agents may cause CO_2 readings to deviate beyond specified tolerances.

Chapter 6: Pneumatics and CO_2 Calibration

Connecting a Non-Recirculating Scavenging System

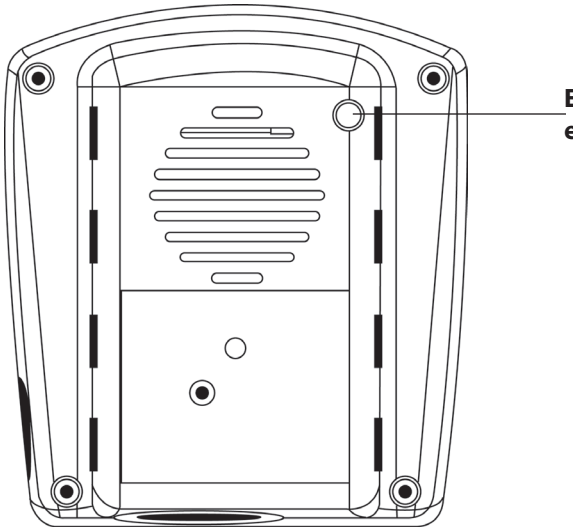


Figure 6.1: Connecting a Non-Recirculating Scavenging System

If desired, connect a non-recirculating scavenging system to the exhaust port on the monitor's rear panel as shown.

CAUTION! When connecting a non-recirculating scavenging system, only use an exhaust line approved by Smiths Medical PM, Inc. Failure to comply may result in damage to the monitor.

Checking for Leaks

1. Pinch the sample line near the moisture filter connection.
2. Make sure the "**OCCLUSION**" message appears in the lower left of the display. If no message appears, go to the *Chapter 12: Troubleshooting* section.

Calibrating the Capnograph

Calibration ensures that the $ETCO_2$ and Inspired CO_2 measurements are accurate. Calibrate the device every 30 days.

NOTE! Use only the calibration gas canister and flow regulator supplied with or specifically intended for use with this device. See *Chapter 13: Supplies and Accessories* for information on ordering calibration gas.

The device has two calibration modes: Low Calibration (LO CAL) and Low/High Calibration (LO/HI CAL). The LO CAL process is required if a significant change in altitude occurs. It is not necessary to remove the device from the patient while performing a LO CAL procedure because a three-way valve closes the patient inlet and opens to room air. The LO/HI CAL procedure requires the delivery of a gas mixture from a canister. When gas canister is empty, dispose of properly.

NOTE! Remove the device from the patient before performing a Low/High Calibration procedure.

Low Calibration

To perform a LO CAL, do the following:

1. Turn on the device.
2. Depress the MENU/ENTER ( ) key. Select **Capnograph**. Select **Low Cal**.
3. A menu screen appears with the message: **CO2 LOW CAL IN PROGRESS**.
4. When the unit is finished, a **CALIBRATION COMPLETE** message will appear.
5. Press the MENU/ENTER ( ) key to return to the Capnograph menu, or press the WAVE/TREND ( ) key to exit all menus.

Low/High Calibration

NOTE! Remove the device from the patient before performing a Low/High Calibration.

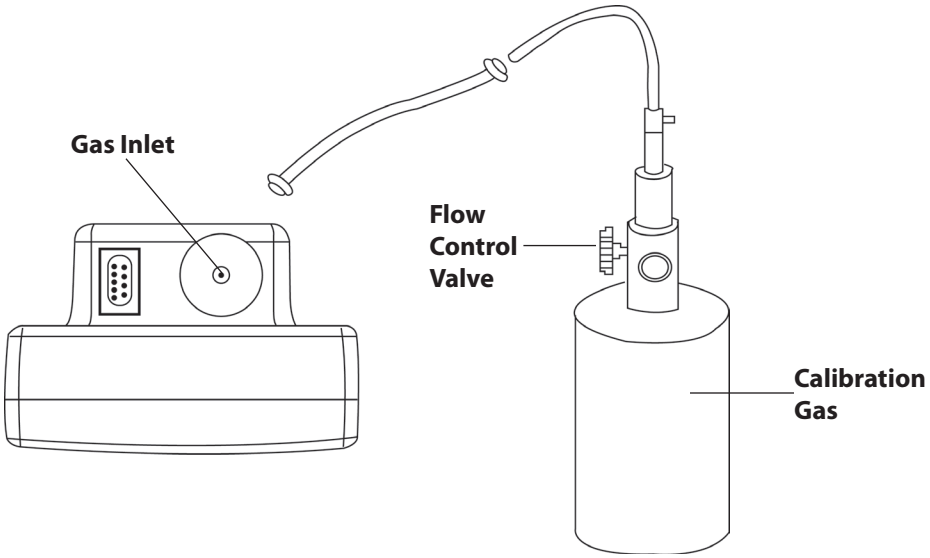


Figure 6.2: Connecting the Calibration Gas

1. Disconnect the patient attachment from the Luer-lock adapter.
2. Turn on the device.
3. Locate the calibration gas canister.
4. Press the MENU/ENTER ( ) key. Select **Capnograph**. Select **Low/High Cal** and follow the directions on the display.
5. After the message **PLEASE TURN ON CAL GAS** appears, quickly open the flow control valve on the calibration gas canister. The valve must be fully opened in less than 30 seconds.
6. When the message **CALIBRATION COMPLETE** appears, close the flow control valve of the calibration gas canister, disconnect the calibration test fixture and exit all menus.
7. Turn the device off, by pressing the OFF/ON % key twice, to ensure the calibration data is saved.

An unsuccessful calibration procedure causes an error message to appear. Operation resumes using the old calibration data. Refer to *Capnograph Messages* in *Chapter 7* for further instructions.

Auto-Zero

The monitor will auto-zero when one of the following conditions occur:

- Within 45 seconds of power up (assuming no occlusion or system faults.
- Two or more hours since last auto-calibration.
- A pressure increase greater then 35 mmHg.

Connecting the Patient

NOTE! Capnograph patient attachments, filters, and sample lines are disposable, single-patient use items. Use a new patient attachment, filter, and sample line for each new patient.

NOTE! Discard and replace the patient attachment if it becomes occluded. If an air leak is noted, check all patient connections. If the air leak persists, discard and replace the patient attachment. Leaks or internal venting of sampled gas may cause lower readings.

Choose the appropriate patient attachment from the following chart, then turn to the figure indicated for attachment instructions. Always inspect the accessories prior to use to ensure device function.

PATIENT	DESCRIPTION	FIGURE
Adult or Pediatric	Nasal Cannula for Adults and Pediatrics Oral/Nasal Cannula for Adults and Pediatrics Ventilator Adapters for Adult and Pediatrics	6.3 6.4 6.5
Infant >3 kg >29 days of age	Nasal Cannula for Infants	6.6

Nasal Cannula for Adults and Pediatrics

1. Insert a cannula into each nostril.
2. Place tubing behind each ear.
3. Slide the plastic ring so it is close to the chin, but not too tight.
4. Connect the filter Luer and twist to tighten.

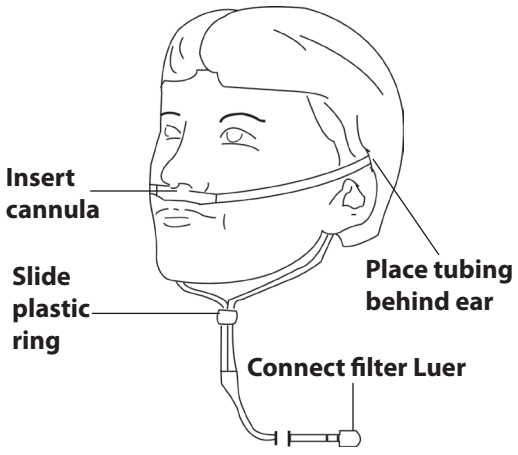


Figure 6.3: Nasal Cannula for Adults and Pediatrics

Oral/Nasal Cannula for Adults and Pediatrics

1. Insert a cannula into each nostril.
2. Mark with a pencil where the tubes meet the lower lip. Remove the cannula. Using a scissors, carefully trim the tubes to the marked line. Replace the cannula.
3. Bend the tubes around the upper lip. These tubes should not go INTO the mouth.
4. Place tubing behind each ear.
5. Slide the plastic ring so it is close to the chin, but not too tight.
6. Connect the filter Luer and twist to tighten.

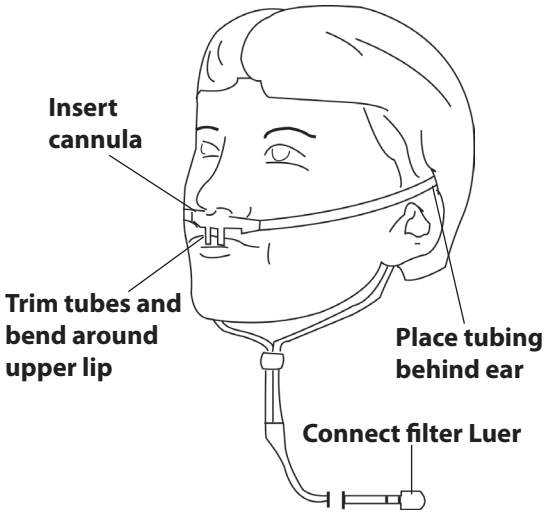


Figure 6.4: Oral/Nasal Cannula for Adults and Pediatrics

Ventilator Adapters for Adults and Pediatrics

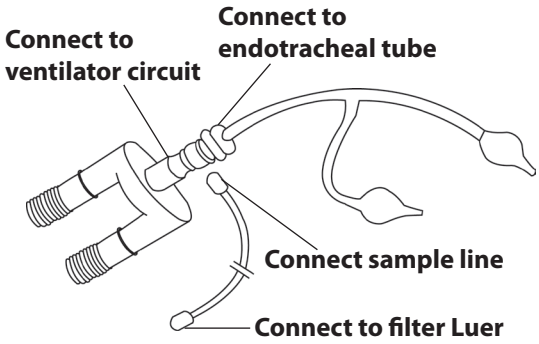


Figure 6.5: Ventilator Adapters for Adults and Pediatrics

1. Connect the large end of the airway adapter to the ventilator circuit.
2. Connect the small end of the airway adapter to the endotracheal tube.
3. Connect the sample line to the airway adapter and twist to tighten.
4. Connect to filter Luer and twist to tighten.

Nasal Cannula for Infants

1. Insert a cannula into each nostril.
2. Place tubing behind each ear.
3. Slide plastic ring so it is close to the chin, but not too tight.
4. Connect to filter Luer and twist to tighten.

WARNING! Do not leave child unattended. Cannula can be possible strangulation hazard.

WARNING! This monitor is not for use on Neonates.

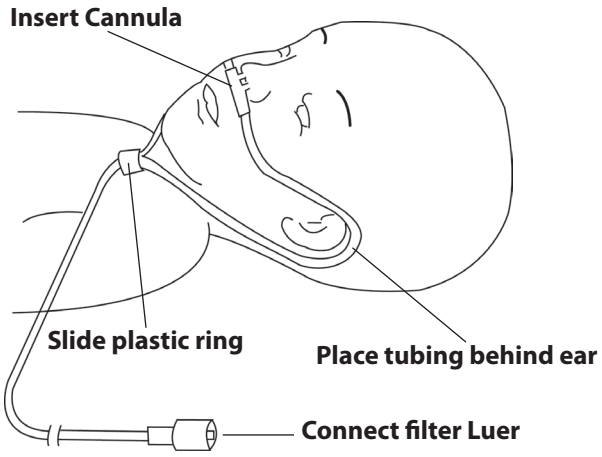


Figure 6.6: Nasal Cannula for Infants

Chapter 7: CO_2 Monitor and Display Menu

General Description

The Capnograph CO_2 monitor noninvasively and continuously monitors and displays $ETCO_2$ and respiration rate (RPM).

The Capnograph flexible alarm system lets you choose alarm parameters and audible tone volumes. You can select the high and low alarm limits for $ETCO_2$ and Respiration, and choose the volume for alarm.

CO_2 Monitor Display

NOTE! InCO_2 is only displayed on the message line, and only if it has exceeded its alarm limit.

NOTE! If measurements are not shown, check the patient attachment and Luer fittings to make sure they are applied correctly. If necessary, check for capnograph messages and see *Capnograph Messages* later in this chapter for help.

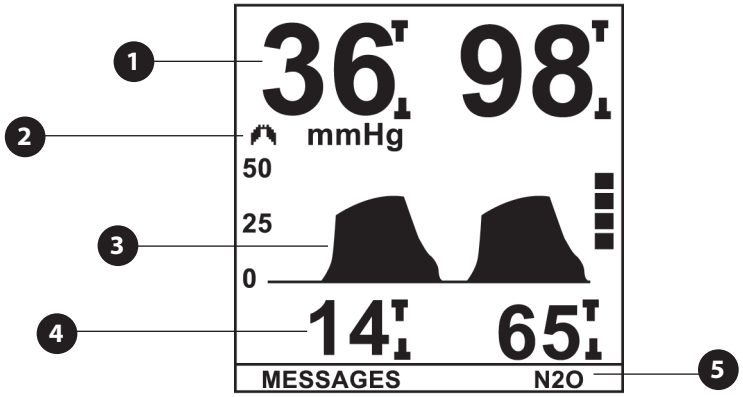


Figure 7.1: Capnograph Display

A few seconds after the patient is attached, the end-tidal CO_2 ($ETCO_2$) and respiration rate (RPM) should be displayed.

1 $ETCO_2$ Measurement

The $ETCO_2$ measurement is labeled on the side of the display. Dashes (--) indicate the measurement is invalid or unavailable. The CO_2 units of measurement are displayed under the numeric value.

2 Breath Indicator

When a breath is detected the Breath Indicator (lungs icon to the left of the CO_2 units of measure label) is bold or fully darkened. Between breaths or exhalation the breath indicator lungs are outlined.

3 CO_2 Waveform

The CO_2 waveform can be displayed by itself. Use the WAVE/TREND ( ) key to select the CO_2 waveform display. The waveform scale and sweep speed are remembered at power down.

4 Respiration Rate Measurement

The respiration rate measurement is labeled RPM (for Respirations per Minute). Dashes (--) indicate the measurement is invalid or unavailable.

5 N_2O Compensation Indicator

A text indicator **N20** is shown at the bottom right of the display if 40% N_2O compensation has been enabled through the CO_2 menu. If the battery is low the N_2O message alternates with the battery indicator.

Capnograph Menu

The Capnograph menu allows the user to view and/or adjust capnograph monitoring settings.

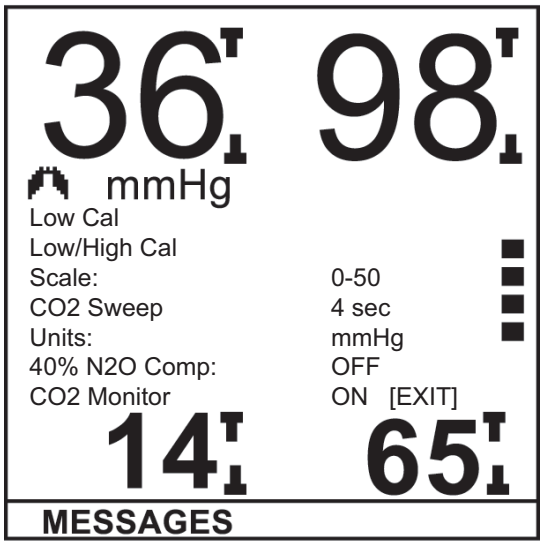


Figure 7.2: Capnograph Menu

Low Cal
Allows the capnograph to perform a low calibration.

Low/High Cal
Allows the capnograph to perform a two-point calibration.

Scale
Indicates the scale of the CO_2 waveform. Allows the scale to be changed.

CO2 Sweep
Indicates the sweep time of the CO_2 waveform. Allows the sweep time to be changed.

Units
Indicates the units of CO_2 measurement. Allows the units to be changed.

40% N2O Comp
Allows the capnograph to compensate in the presence of N_2O (nitrous oxide).

CO2 Monitor
Indicates whether the CO_2 parameter is on or off. Allows CO_2 monitoring to be turned on or off.

Turning Capnograph Monitoring On and Off

When turned off, displays, indicators, and alarms related to the parameter are disabled. The $ETCO_2$ and Resp Rate parameters occupy space on the display and in the serial output, but their values are shown as dashes. The CO_2 waveform area shows a monitor off message.

To turn capnograph monitoring on or off, do the following:

1. From the Main menu, select the desired parameter's menu item: **Capnograph**.
2. In the parameter's menu, select the **CO2 Monitor on/off** item.
3. Press MENU/ENTER ( ) and use the ARROWS (∧ or ∨) to adjust the setting to **ON** or **OFF**.
4. Select **[EXIT]** or press WAVE/TREND ( ) to exit menus.

Adjusting Waveform Sweep Time or Scales

The sweep time and scales for the $C0_2$ waveform can be adjusted as follows:

1. The CO_2 waveform sweep time and display scales can be adjusted in the Capnograph menu.

2. Each parameter's trend display scales can be adjusted separately through the Trends, Set Scales menu. See *Chapter 9: Trends*.

Capnograph Messages

Alarm messages related to the capnograph are shown on the bottom message line at the lower left of the display. If there are several messages to be displayed, they alternate, showing one message every second.

If the capnograph monitoring is disabled through menus, a message is displayed in the CO_2 waveform area.

During calibration, status messages are shown in the calibration menu area.

High and Medium Priority Alarm Messages

ETCO2 > (x)
Indicates the $ETCO_2$ measurement is equal to or higher than the high $ETCO_2$ alarm limit. (x) is the high alarm limit setting.

ETCO2 < (x)
Indicates the $ETCO_2$ measurement is equal to or lower than the low $ETCO_2$ alarm limit. (x) is the low alarm limit setting.

inCO2 = (y)
Indicates the inspired CO_2 measurement is equal to or higher than the high $inCO_2$ alarm limit. (y) is the current inCO2 value.

RESP > (x)
Indicates the respiration rate measurement is equal to or higher than the high respiration rate alarm limit. (x) is the high alarm limit setting.

RESP < (x)
Indicates the respiration rate measurement is equal to or lower than the low respiration rate alarm limit. (x) is the low alarm limit setting.

Low Priority Alarm Messages

OCCLUSION
Indicates the monitor has detected a blockage in the pneumatic circuit or patient line. See *Chapter 12: Troubleshooting*.

Status Message

CO2 Monitor: OFF
Indicates the capnograph function has been disabled through menus. This message replaces the CO_2 waveform.

NOTE! Do not use monitor while nebulized medications are being administered.

Calibration Messages

Calibration Complete
Indicates the calibration was successfully completed.

CO2 Sensor Error
Indicates the high CO_2 calibration was not within an acceptable range. Verify the proper calibration gas is being used, and calibrate again. If the message persists, contact your authorized repair center.

ERROR: High CO2 Unstable
Indicates the high CO_2 calibration was inconsistent. Calibrate again. If the message persists, contact your authorized repair center.

Chapter 8: Using the Oximeter Option

NOTE! Alarm limit settings are retained during power cycles, except for the following.

NOTE! (For optional oximeter) If either the high or low SpO_2 limit is set below 80% when the device is powered down, the limit will reset to 85% or higher, when power is returned to the device.

General Description

The Capnograph Oximeter noninvasively and continuously monitors and displays arterial blood oxygen saturation (%SpO_2), pulse rate, and plethysmogram. The Capnograph beeps with each pulse beat. The pitch of the pulse beep depends on the SpO_2 value; the higher (or lower) the %SpO_2 value, the higher (or lower) the pulse beep pitch.

The Capnograph flexible alarm system lets you choose alarm parameters and audible tone volumes. You can select the high and low alarm limits for SpO_2 and pulse rate, and independently choose the volume for alarm and pulse beep tones.

Pulse Oximetry Theory of Operation

The pulse oximeter determines %SpO_2 and pulse rate by passing two wavelengths of low intensity light, one red and one infrared, through body tissue to a photodetector. Information about wavelength range can be especially useful to clinicians. Wavelength information for this device can be found in the *SpO_2 Specifications* section of this manual.

Pulse identification is accomplished by using plethysmographic techniques, and oxygen saturation measurements are determined using spectrophotometric oximetry principles. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the sensor placement, the intensity of the light sources, and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissues.

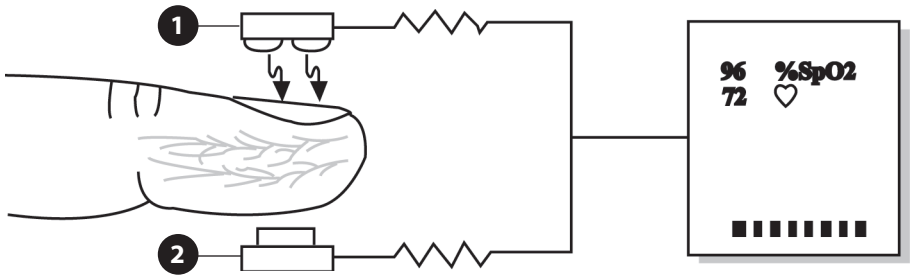


Figure 8.1: Pulse Oximetry Theory of Operation

1. **Low intensity Red and Infrared LED light sources**
2. **Detector**

Oximetry processes these signals, separating the time invariant parameters (tissue thickness, skin color, light intensity, and venous blood) from the time variant parameters (arterial volume and SpO_2) to identify the pulses and calculate functional oxygen saturation. Oxygen saturation calculations can be performed because blood saturated with oxygen predictably absorbs less red light than oxygen-depleted blood.

WARNING! Since measurement of SpO_2 depends on a pulsating vascular bed, any condition that restricts blood flow, such as the use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate SpO_2 and pulse rate readings.

WARNING! Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO_2 and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

WARNING! Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, patent blue V (PBV), and fluorescein, may adversely affect the accuracy of the SpO_2 reading.

WARNING! Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin (with CO-poisoning) or methemoglobin (with sulfonamide therapy), will affect the accuracy of the SpO_2 measurement.

WARNING! SpO_2 measurements may be adversely affected in the presence of high ambient light. If necessary, shield the sensor area (with a surgical towel, for example).

WARNING! Remove fingernail polish or false fingernails before applying SpO_2 sensors. Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.

WARNING! Tissue damage may result from overexposure to sensor light during photodynamic therapy with agents such as verteporphin, porfimer sodium and metatetrahydroxyphenylchlorin (mTHPC). Change the sensor site at least every hour and observe for signs of tissue damage. More frequent sensor site changes or inspections may be indicated depending upon the photodynamic agent used, agent dose, skin condition, total exposure time or other factors. Use multiple sensor sites.

Oximeter Display

A few seconds after the patient is attached, the SpO_2 measurement, pulse rate measurement, and pulse bargraph should be shown.

NOTE! If measurements are not shown, check the patient attachment to make sure it is applied correctly. Also check for oximeter messages in the high priority alarm and low priority alarm message area and see *Oximeter Messages* later in this chapter for help.

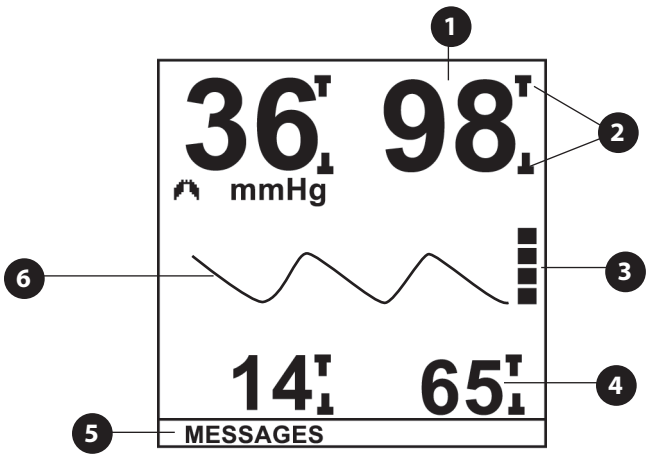


Figure 8.2: Oximeter Display

1 %SpO_2 Measurement

The %SpO_2 measurement is shown. Dashes (---)indicate the measurement is invalid or unavailable.

2 Alarm Limit Indicators

The SpO_2 and pulse rate digits have a corresponding set of alarm limit indicators. The uppermost indicator represents the high alarm limit; the lower most indicator represents the low alarm limit. For more about alarm indicators, see *Chapter 4: Alarms*.

The following alarm limits are provided for oximeter measurements:

- High and low %SpO_2.
- High and low pulse rate.

For instructions on adjusting or viewing alarm limits, see *Chapter 4: Alarms*.

3 Pulse Strength Bargraph

Indicates the patient's pulse activity and strength. The bargraph is logarithmically scaled to indicate a wide range of pulse strengths.

4 Pulse Rate Measurement

The pulse rate measurement is labeled "BPM" (for beats per minute). Dashes (---) indicate the measurement is invalid or unavailable.

5 Messages

Oximeter messages appear in the message area at the lower left of the display. For details on the oximeter messages, see *Oximeter Messages* later in this chapter.

6 Plethysmogram

The plethysmogram is shown, assuming it is assigned to a trace. Press the WAVE/TREND ( ) key to select the plethysmogram display.

Oximeter Menu

The oximeter menu allows the user to view and/or adjust oximeter monitoring settings.

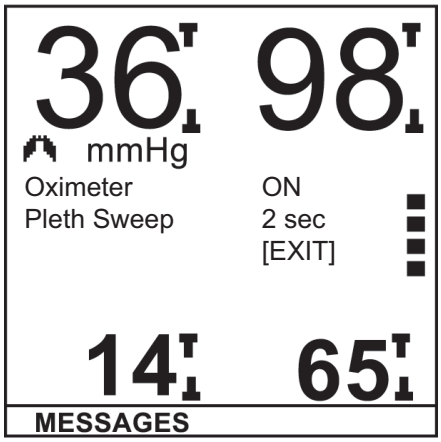


Figure 8.3: Oximeter Menu

Oximeter

Indicates whether the oximetry parameter is on or off. Allows the oximetry parameter to be turned on or off.

NOTE! Turning off the Oximetry parameter turns off the plethysmogram, %SpO_2, pulse rate, and pulse strength measurements.

Pleth Sweep

Indicates the plethysmogram sweep time. Allows the sweep time to be adjusted.

Turning Oximeter Monitoring On and Off

When turned off, displays, indicators, and alarms related to the oximetry parameter are disabled. The SpO_2 and Pulse Rate occupy space on the display and in the serial output, but their values are shown as dashes (---). The oximetry waveform area shows the message **oximeter off**.

To turn a parameter's monitoring on or off, do the following:

1. From the Main menu, select the desired parameter's menu item: **Oximeter**.
2. In the parameter's menu, select the **Oximeter on/off** item.
3. Press MENU/ENTER ( ) and use the ARROWS (^ or v) to adjust the setting to **ON** or **OFF**.
4. Select **[EXIT]** or press WAVE/TREND ( ) to exit menus.

Adjusting Waveform Sweep Time

The sweep time, and scales for waveforms can be adjusted as follows:

1. The plethysmogram sweep time can be adjusted using the Oximeter menu item: **Pleth Sweep**
2. Each parameter's trend display scales can be adjusted separately through the **Trends**, **Set Scales** menu.

Adjusting the Pulse Beep Volume

1. Select **Volume** from the Main menu.
2. Select the **Pulse** item.
3. Press the MENU/ENTER ( ) key to select the item. Use the ARROW (^ or v) keys to adjust the pulse volume. Press MENU/ENTER ( ) to set the value.

NOTE! The pulse beep sounds while adjusting the volume.

4. Select **[EXIT]** or press WAVE/TREND ( ) to exit the menu.

Oximeter Messages

Oximeter messages are shown in the message area at the lower left of the display. The displayed messages are prioritized to show what is most important at the top.

High Priority Alarm Messages

SPO2 > (x)
Indicates the SpO_2 measurement is equal to or higher than the high SpO_2 alarm limit. (x) is the high alarm limit setting.

SPO2 < (x)
Indicates the SpO_2 measurement is equal to or lower than the low SpO_2 alarm limit. (x) is the low alarm limit setting.

Pulse > (x)
Indicates the pulse rate measurement is equal to or higher than the high PULSE alarm limit. (x) is the high alarm limit setting.

Pulse < (x)
Indicates the pulse rate measurement is equal to or lower than the low PULSE alarm limit. (x) is the low alarm limit setting.

LOST PULSE
Indicates that the sensor no longer detects a pulse while the sensor is attached to the patient, and a pulse was previously detected. Check the patient. Make sure the sensor is properly positioned on the patient.

Low Priority Alarm Messages

SPO2 SENSOR!
Indicates the SpO_2 sensor is disconnected from the monitor or the patient. Make sure the patient cable and sensor connectors are all firmly seated. Make sure the sensor is positioned properly on the patient. If the message persists, contact your authorized repair center.

SPO2 LOST
Indicates the oximeter circuitry could not measure the patient's SpO_2 or pulse rate. Make sure the sensor is positioned properly on the patient.

Messages

SPO2 SEARCH
Indicates the oximeter is adjusting to the patient's signal. If this message persists, make sure the sensor is positioned properly on the patient.

SPO2 ERROR
Indicates the oximeter has failed. Contact a Smiths Medical PM, Inc. service representative.

NOTE! If the message "SpO2 SEARCH" stays up for 10 seconds or more, a system low priority alarm will sound.

Attaching the Patient - Oximetry

Choose the Sensor

PATIENT	SITE	CAT. NO. & DESCRIPTION
Adult >45 kg	Finger	3044: Sensor, Adult (reusable) 3444: Sensor, Comfort Clip® (reusable)
	Finger or Toe	3043: Sensor, Universal 'Y' (reusable) 1300: Sensor, Adult (disposable)
	Ear	3078: Sensor, Ear (reusable)
Pediatric 15-45 kg	Finger	3044: Sensor, Adult (reusable) (>20 kg) 3444: Sensor, Comfort Clip® (reusable) 3178: Sensor, Pediatric (reusable) (5-45 kg)
	Finger or Toe	3043: Sensor, Universal 'Y' (reusable) 1301: Sensor, Pediatric (disposable)
	Ear	3078: Sensor, Ear (reusable)
Infant 3-15 kg	Hand or Foot	3043: Sensor, Universal 'Y' (reusable)
	Toe	3025: Sensor, Wrap, Infant (reusable)
	Finger or Toe	1303: Sensor, Infant (disposable)
Small Infant < 3 kg	Hand or Foot	1302: Sensor, Neonate (disposable)
	Foot	3026: Sensor, Wrap, Neonate (reusable)

**The BCI® 1302 and 3026 oximetry sensors should not be used on neonatal patients with the Capnograph monitor. Testing has not been conducted for the Capnograph for patients less than 30 days old. These sensors may, however, be used on older patients.*

Clean or Disinfect the Reusable Sensors

If you choose a reusable sensor, clean or disinfect the sensor before attaching a new patient.

WARNING! Do not autoclave, ethylene oxide sterilize, or immerse the sensors in liquid.

CAUTION! Unplug the sensor from the monitor before cleaning or disinfecting.

Clean the sensor with a soft cloth moistened in water or a mild soap solution. To disinfect the sensor, wipe the sensor with isopropyl alcohol.

Check Sensor Integrity

Before the sensor is attached to the patient, check the integrity of the sensor, oximetry cable, and oximeter as follows:

1. Make sure the red light in the sensor is illuminated.
2. Make sure the **Sp02 SENS0R!** message is displayed on the EL Display.

NOTE: Obstructions or dirt on the sensor's red light or detector may cause the checks to fail. Make sure there are no obstructions and the sensor is clean.

3. Connect the sensor as follows:
   a. For "Y" sensors, wrap sensors, and disposable sensors, align the sensor's red light with the detector so they are less than 1/8 inch away from each other. Make sure the **Sp02 SENS0R!** message is displayed on the message area of the EL Display.
   b. For the finger sensor and ear sensor, make sure the **Sp02 SENS0R!** message is displayed in the message area of the EL Display.

Attach the Sensor to the Patient

WARNING! Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

WARNING! When attaching sensors with Microfoam® tape, do not stretch the tape or attach the tape too tightly. Tape applied too tightly may cause inaccurate readings and blisters on the patient's skin (lack of skin respiration, not heat, causes the blisters).

WARNING! Failure to carefully route the cable from the sensor to the monitor may allow the patient to become entangled in the cable, possibly resulting in patient strangulation. Route the cable in a way that will prevent the patient from becoming entangled in the cable. If necessary, use tape to secure the cable.

Finger Sensor for Adult or Pediatric Finger

Attach the finger sensor to the patient as shown. Be sure to fully insert the patient's finger into the sensor. For patients with long fingernails, use the universal 'Y' sensor.

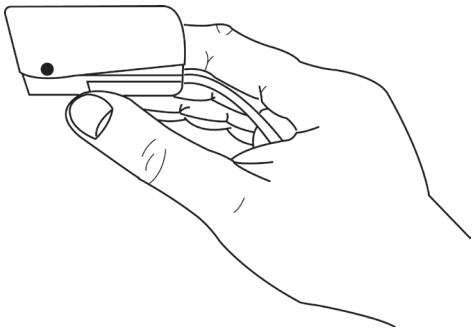


Figure 8.4: Attaching the Finger Sensor

WARNING! Incorrectly applied sensors may give inaccurate readings. ⚠ Refer to the sensor insert for proper application instructions.

Checking the Oximeter's Performance

Pulse oximeters do not require user calibration. If checking the function of the device is desired, an optional Oximetry/ECG Patient Simulator (SMPM catalog number 1606) is available as an accessory. The simulator attaches to the oximeter in place of the sensor or oximetry cable. It provides a known SpO_2 and pulse rate signal to the oximeter. This allows the oximeter's performance to be checked.

NOTE! The 1606 Oximetry/ECG Patient Simulator does not calibrate the monitor; the monitor does not require calibration. The 1606 provides a known SpO_2 and pulse rate to the monitor that allows you to check the monitor's performance.

NOTE! The 1606 Oximetry/ECG Patient Simulator cannot be used to assess the accuracy of a pulse oximeter and/or sensor.

NOTE: ⚠ Follow the instructions included with the 1606 Oximetry/ECG Patient Simulator.

Chapter 9: Trends

Press the WAVE/TREND ( ) key to cycle through displays until a Trend graph is shown. Trends can be displayed for $ETCO_2$, respiration rate, $\%SpO_2$ or pulse rate. The following diagram and descriptions outline the trend display's features.

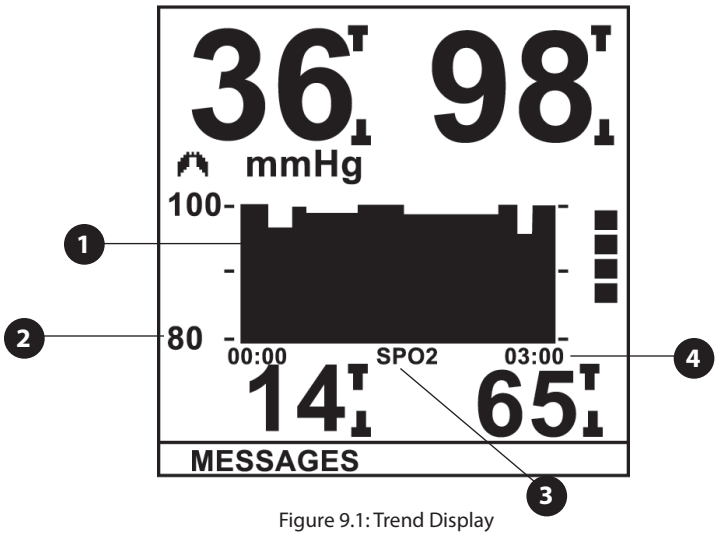


Figure 9.1: Trend Display

1 Trend Graph

The trend graph is displayed here. Displayed trends show elapsed time, that is, what happened over the selected minutes or hours. Gaps will appear in the trend graph for the length of time the parameter data has been invalid, or if the value was less than the lower scale setting. A value greater than the upper scale limit is shown as a full scale value.

2 Scale

The trend's scale is shown on the left side of the trend display.

3 Trended Parameter

The name of the trended parameter is displayed here.

4 Trend Time

The time scale of the trend is displayed here. Trend data and time are continuously updated.

When WAVE/TREND ( ) is selected, the previously viewed trend is displayed. To view a different trend, press an ARROW (^ or v) key until the desired trend is displayed. Press WAVE/TREND ( ) to return to viewing waveforms again. Trend times and scales are selected with the Trends menu item (see *Trends Menu*).

Trends Menu

The Trends menu allows the user to view and/or adjust the trend settings.

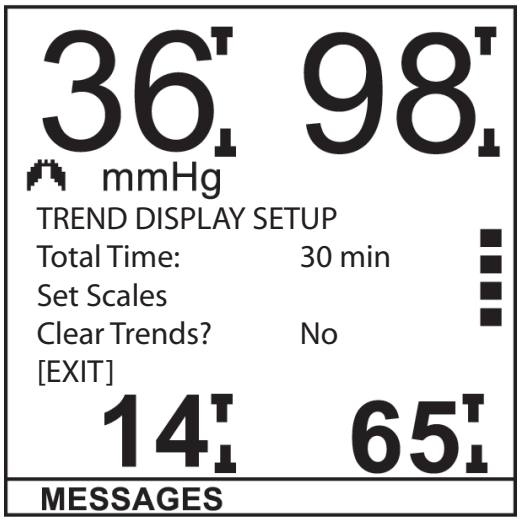


Figure 9.2: Trends Menu

Total Time
Adjusts the time span of the trend display. The options are 30 minutes or 3 hours.

Set Scales
Displays a menu that allows a separate unit scale to be selected for each parameter.

Clear Trends?
Select **Yes** to erase trend memory.

NOTE! "Yes" means all trended data will be erased when the trend menu is exited.

Trend data will not be lost if this selection is set back to **No** before **[EXIT]** is selected, and the monitor is not powered down.

NOTE! Turning off the monitor or loss of supply mains will result in the loss of trend data.

Chapter 10: Printer Output

Printer Setup

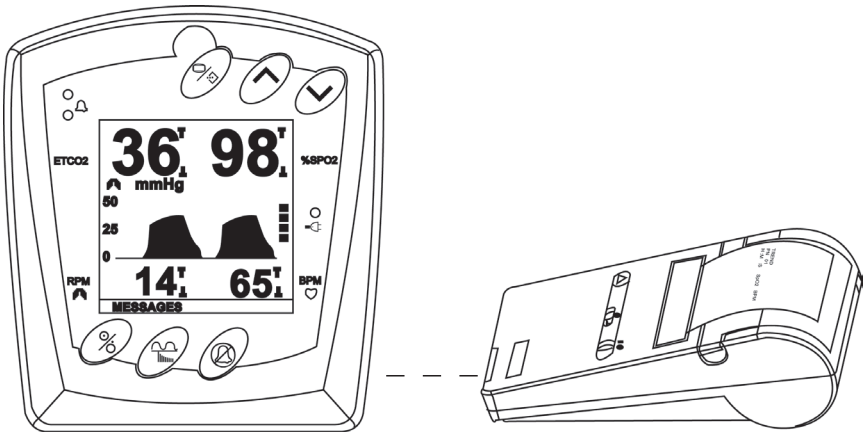


Figure 10.1: Printer Setup

The Capnograph communicates to the Martel MCP8850B printer through the infrared serial port. Align the infrared serial ports as shown in the above illustration. Optimal distance from port to port is 10.2 -15.2 cm (4 – 6 inches). When Capnograph and printer are properly aligned proceed to the Printer menu on the Capnograph.

WARNING! When connecting to or communicating with this monitor, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. Accessory equipment connecting to or communicating to the monitor's data interface must be certified according to the respective IEC standards, i.e., IEC 60950 for data-processing equipment or IEC 601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC 601-1-1 systems requirements.

WARNING! IEC 60950 approved equipment including the Martel MCP8850B printer must be placed outside of the "patient environment". The patient environment is defined as an area 1.5m (4.92 feet) from the patient.

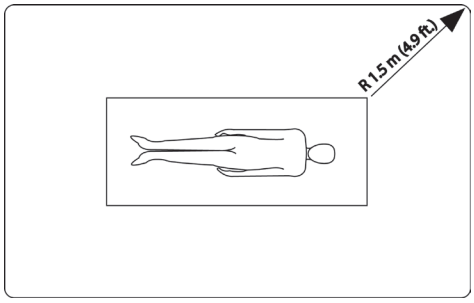


Figure 10.2: Patient Environment

Printer Menu

The Printer menu allows the user to select a data format for output to the infrared serial port, as well as select the output interval and/or the amount of data to send. This data can be output to a compatible printer.

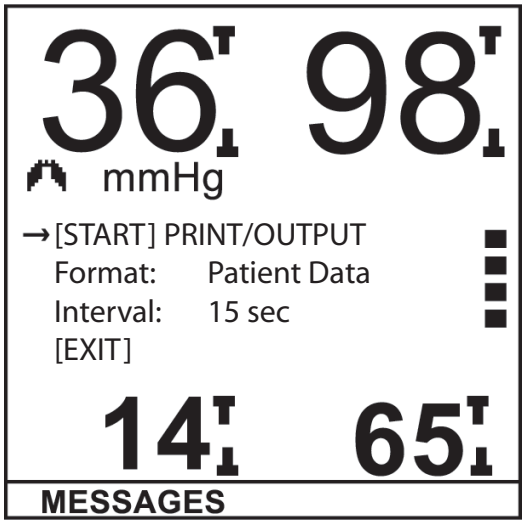


Figure 10.3: Printer Output Menu, Patient Data

START/STOP
Select this to enable/disable serial output. If no output is currently in progress, this shows **START**. If output is in progress, this shows **STOP**.

Data Format
Shows data output format, **PATIENT DATA** or **TREND DATA**.

Interval
Shows the amount of time between data log outputs.

Printer/Output

The serial output data format and output interval or amount can be changed only if no print output is in progress. To change the data format selection:

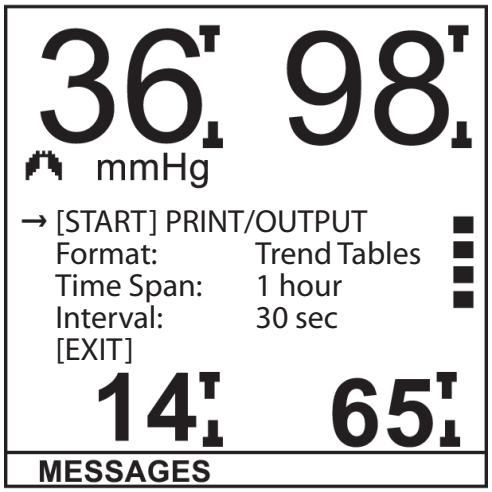


Figure 10.4: Printer Output Menu, Trend Tables

Select **Printer** from the Main Menu. If **[START]** is displayed, then no print output is currently in progress, so proceed with step 2. Otherwise, **[STOP]** is shown and you must select **STOP** to halt the current output before the serial output data settings can be changed.

To change the data format (Patient Data or Trend Tables):

1. Use the ARROW (∧ or ∨) keys to point to the **Format** item, then press MENU/ENTER ( ).
2. Use the ARROW (∧ or ∨) keys to switch between formats. When the format changes, the menu item below it changes.

If **Patient Data** is selected, the menu item displayed below it is: **Interval**.

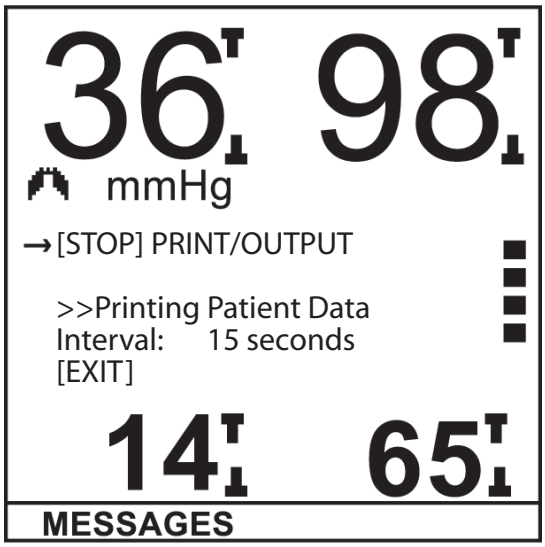


Figure 10.5: Printing Patient Data Status Menu

If **Trend Tables** is selected, the menu items below are: **Time Span** and **Interval**.

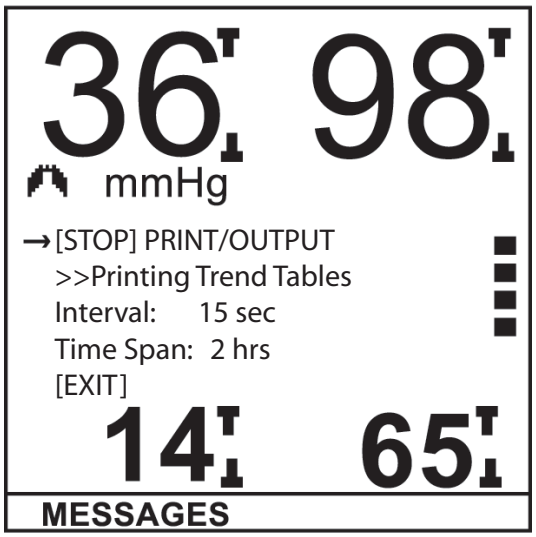


Figure 10.6: Priority Trend Table Status

3. Press MENU/ENTER ( ) to accept the selection.

To change the output interval or trend time span:

1. Use the ARROW (^ or v) keys to point to **Interval** (for Patient Data Format) or **Time Span** (for Trend Tables format), then press MENU/ENTER ( ).

2. Use the ARROW (^ or v) keys to change the value.

3. Press MENU/ENTER ( ) to accept the selection.

4. When the output format has been set, select **[START]** to enable the serial output. At this point, the **[START]** field will change to **[STOP]**, and the message "**Printing...**" will be displayed in the menu area.

5. Select **[EXIT]** or press WAVE/TREND ( ) to exit menus. If serial output is in progress, exiting menus will not stop it.

To STOP serial output:

1. Select **Printer** from the main menu.

2. Select **[STOP]** (if it is shown.)

Output Examples

Patient Data

A real-time Patient Data sample is output through the infrared port, one table per output interval. The time interval between tables is selected in the Printer menu. Each line of text in the patient data table ends with a carriage return, line feed.

Sample Output (including optional oximetry)

```
PATIENT DATA
Sample Interval: 15 secs
Relative Time    00:00:15
ETCO2            28 mmHg
inCO2            03 mmHg
Resp Rate        06 rpm
SpO2             98 %SpO2
Pulse            74 bpm
40% N2O/Comp:    No
```

Trend Table Data

Trend data is output in tabular text format, one table per trend data record, starting at the oldest record. The number of records printed depends on the time span selected in the Printer menu. For example, if Time Span = 2 hours, then two hours of accumulated trend data records will be printed.

Each line of text in the trend tables ends with a carriage return, line feed.

Each new block of many trend data records has the following title information:

Sample Output (including optional oximetry)

```
TREND DATA
Sample Interval: 15 secs
Time Span         1 min
Relative Time    00:50:15
ETCO2            28 mmHg
inCO2            03 mmHg
Resp Rate        06 rpm
SpO2             98 %SpO2
Pulse            74 bpm
```

This page is intentionally left blank.

Chapter 11: Routine Maintenance

Charging the Battery

Charge the battery after the monitor is used under battery operation, when the **LOW BATTERY** message is displayed, or after long term storage. Remove the battery from the device. Place the battery in the external charger unit. Verify the green "CHARGING" LED is lit.

After 2.5 hours, the battery is fully charged, indicated by the "CHARGE COMPLETE" LED. To ensure continuous use of the Capnograph, with battery power, the purchase of a second battery is recommended. Please refer to Appendix A: Supplies and Accessories, for more information.

CAUTION! The monitor contains a 6 hour Lithium-Ion battery. If the battery fails to hold a charge or otherwise becomes inoperable, the battery should be replaced and the old battery should be disposed of properly. Consult local officials for information about the proper disposal of the Lithium-Ion battery. Smiths Medical PM, Inc. cannot dispose of monitor batteries.

Cleaning and Disinfecting

CAUTION! Do not immerse the monitor or any of its accessories in liquid. Do not autoclave or ethylene oxide sterilize the monitor or any of its accessories. Unplug the external charger before cleaning or disinfecting the monitor or its accessories.

CAUTION! Do not allow isopropyl alcohol or water to enter any of the openings in the monitor. Evidence that liquid has been allowed to enter the monitor voids the warranty.

CAUTION! Before cleaning or disinfecting the MCP8850B printer, unplug the AC adapter, remove the batteries, and remove the paper.

CAUTION! Should the device become wet, wipe off all moisture and allow sufficient time for drying before operating.

Clean the surfaces of the monitor and the accessories with a soft cloth moistened in a mild soap solution. If disinfecting is required, wipe the surfaces with isopropyl alcohol then wipe with a water moistened soft cloth.

Maintenance Chart

ITEM	ACTION	INTERVAL
Battery	Charge	When LOW BATTERY message is displayed. After continuous use under battery power.
The monitor's surfaces.	Clean or disinfect.	As required. **Caution! Do not allow isopropyl alcohol or water to enter any of the openings in the monitor. Evidence that liquid has been allowed to enter the monitor voids the warranty.**
SpO_2 sensors.	Inspect and change patient site. Clean or disinfect.	Every 4 hours. When attaching a new patient.
Capnograph patient attachment.	Discard the capnograph patient attachment.	When finished monitoring the patient. The capnograph patient attachments are disposable, single-use items. When the patient attachment becomes occluded or has an air leak.
Moisture filter.	Discard and replace the moisture filter.	The moisture filter occludes when it is full.
Capnograph calibration.	Perform a Low/High calibration.	Once every month.
Pneumatic system.	Check pneumatic system for leaks.	After replacing the moisture filter and Capnograph patient attachment. At least once every two weeks.
Calibration gas canister.	Discard and replace the calibration gas canister.	When the gas pressure reading is 20 psi or less as shown on the flow control valve's pressure gauge.

CAUTION! Follow local governing ordinances and recycling instructions regarding disposal and recycling of device components.

Long Term Storage

WARNING! Remove the device batteries prior to long term storage.

Storage Facility:	Indoor
Temperature:	-40 to +75° C (-40 to +167° F)
Relative Humidity:	10 to 95 %, non-condensing
Periodic Inspection:	None required
Special Procedures:	Store the monitor and accessories in the original packing materials and shipping carton.

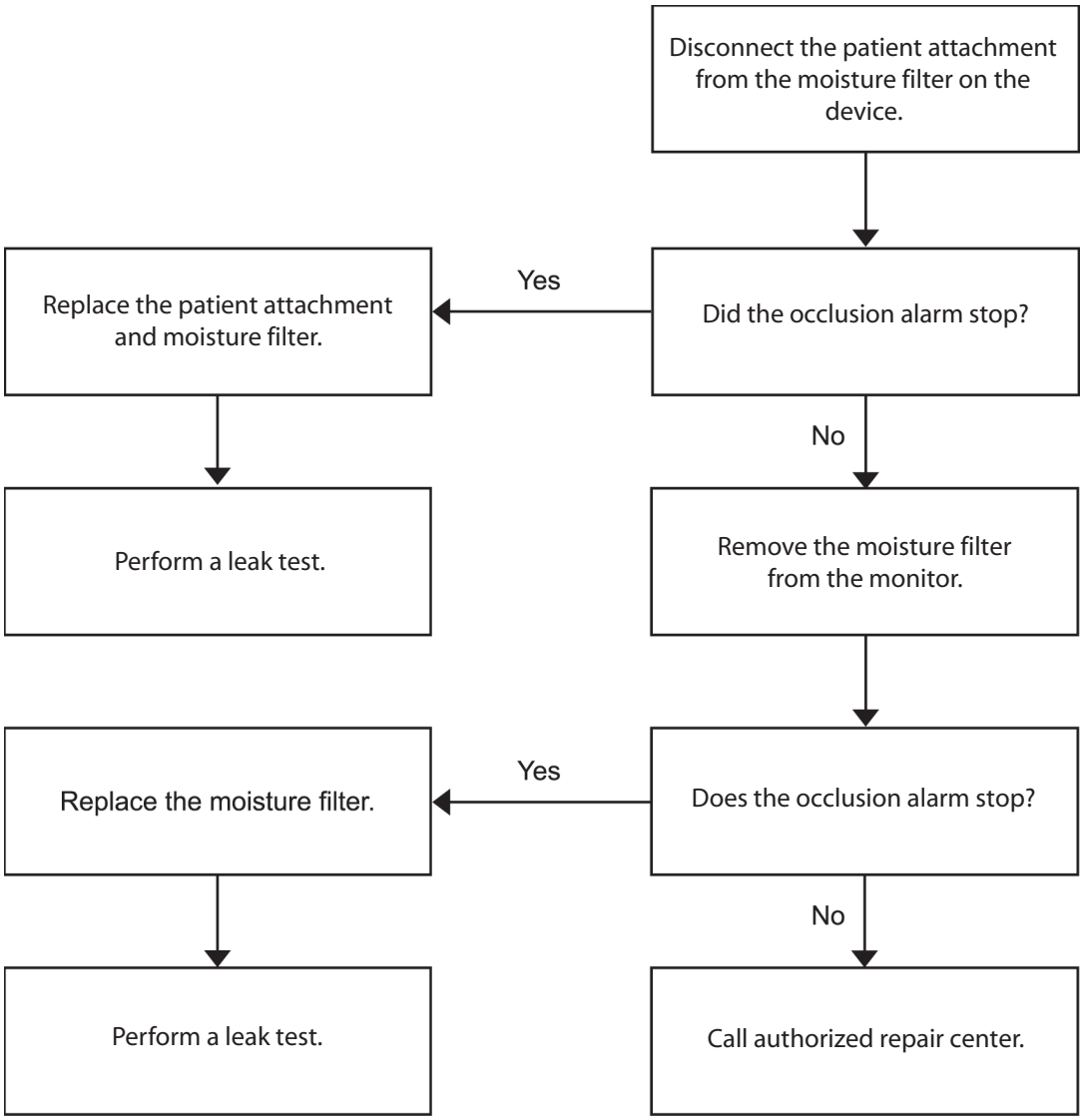
Chapter 12: Troubleshooting

PROBLEM	POSSIBLE CAUSE	SOLUTION
SPO2 SENSOR is displayed.	Sensor not connected to monitor or patient.	Connect the sensor to the patient cable and connect the patient cable to the monitor. Attach the sensor to the patient.
	Sensor improperly positioned on patient.	Reposition the sensor on the patient.
	Incorrect sensor for application.	Choose the correct sensor for the application.
	Defective sensor or patient cable.	Change the sensor or contact Smiths Medical PM, Inc. service department or recharge battery.
Unit operates when connected to external charger, but not on battery power.	Battery shelf life exceeded or battery not charged.	Contact Smiths Medical PM, Inc. service department.
Display does not light.	If operating on battery, battery may need charging.	Recharge battery.
Green External Power LED not lit.	Battery eliminator not properly seated in unit.	Reseat battery eliminator in unit.
No pulse registering on bargraph.	Sensor or patient cable disconnected from monitor.	Check connections to patient cable and sensor.
	Sensor incorrectly positioned.	Reposition sensor on patient.
	Poor patient perfusion.	Reposition sensor on patient.
	Defective sensor or patient cable.	Try a new sensor or contact Smiths Medical PM, Inc. service department.
Pulse rate erratic, intermittent or incorrect.	Sensor incorrectly positioned.	Reposition sensor on patient.
	Poor patient perfusion.	Reposition sensor on patient.
	Patient motion.	Patient must be still for monitor to function properly. Place extremity on a pillow that acts as a "buffer" to motion.
	Ambient light.	Shield with towel.
HIGH CALIBRATION REQUIRED, appears at startup.	Monitor needs calibration.	Contact Smiths Medical PM, Inc. service representative.
NEW CO2 SENSOR, appears at startup.	New CO_2 sensor or new software installed.	Contact Smiths Medical PM, Inc. service representative.
CO2 BENCH ERROR, appears at startup.	The CO_2 Bench is not working.	Contact Smiths Medical PM, Inc. service representative.
SPO2 ERROR, appears at startup.	The Oximeter board has failed.	Contact Smiths Medical PM, Inc. service representative.
User settings lost, reset to default.	User data has been corrupted and reset to factory defaults.	Update any applicable user setting through the menu structure.

CAUTION! The monitor should be operated from its internal power source if the integrity of the protective earth conductor is in doubt.

Troubleshooting the Occlusion Low Priority Alarm

Most occlusions are automatically cleared within a minute. If occlusion cycles occur frequently or the occlusion low priority alarm persists, use the following chart to find and repair the problem.


Disconnect the patient attachment from the moisture filter on the device.
Did the occlusion alarm stop?
Yes
Replace the patient attachment and moisture filter.
Perform a leak test.
No
Remove the moisture filter from the monitor.
Does the occlusion alarm stop?
Yes
Replace the moisture filter.
Perform a leak test.
No
Call authorized repair center.

Repairs of Smiths Medical PM, Inc. devices under warranty must be made at authorized repair centers. If the device needs repair, contact your local distributor or Smiths Medical PM, Inc. service department. When calling, have the device's model and serial number ready.

Smiths Medical PM, Inc.
N7W22025 Johnson Drive
Waukesha, WI USA 53186-1856
Phone: (262) 542-3100
Toll-Free: (800) 558-2345
Fax: (262) 542-0718
e-mail address: info.pm@smiths-medical.com

Chapter 13: Supplies and Accessories

CAT. NO.	DESCRIPTION	QTY
1100	Adapter, Airway, Straight, w/o filter, 12.7 ID x 15 OD (mm)	10/pkg
1101	Cannula + Sample Line, Nasal O_2, Adult	10/pkg
1102	Cannula + Sample Line, Nasal O_2, Pediatric	10/pkg
1105	Adapter, Airway, Straight, w/ filter, 12.7 ID x 15 OD (mm)	10/pkg
1114	Adapter, Airway, Dual Port, Straight	10/pkg
1121	Cannula + Sample Line, Oral/Nasal CO_2, Adult	10/pkg
1123	Sample Line, Oral/Nasal CO_2, Adult	10/pkg
1124	Sample Line, Oral/Nasal CO_2, Pediatric	10/pkg
1129	Sample Line, Nasal CO_2, Adult	10/pkg
1130	Sample Line, Nasal CO_2, Pediatric	10/pkg
1131	Sample Line, Nasal CO_2, Infant	10/pkg
1140	CO_2 Sample Line, Extension, 4.6 m (15 feet)	10/pkg
1151	Adapter, Airway, w/o filter, Pediatric, 12.7 ID x 15 OD (mm)	10/pkg
1152	Adapter, Airway, w/ filter, Pediatric, 12.7 ID x 15 OD (mm)	10/pkg
1300	Sensor, Oximetry, Disposable, Adult Finger	10/box
1301	Sensor, Oximetry, Disposable, Pediatric Finger, 15-45 kg.	10/box
1302	Sensor: Oximetry, Disposable, Neonate, < 3 kg. *	10/box
1303	Sensor, Oximetry, Disposable, Infant Finger, 3-15 kg.	10/box
1606	Simulator, Oximeter/ECG	each
1894	Manual, Operation, (Capnocheck® II)	each
1895	Manual, Service, (Capnocheck® II)	each
3025	Sensor, Oximetry, Wrap, Infant, 3-15 kg.	each
3026	Sensor, Oximetry, Wrap, Neonate, <3 kg. *	each
3043	Sensor, Oximetry, Universal 'Y'	each
3044	Sensor, Oximetry, Finger	each
3049	Strips, Adhesive	40/pkg
3078	Sensor, Oximetry, Ear	each
3134	Tape, Attachment, Neonate	50/pkg
3135	Tape, Attachment, Infant	50/pkg
3136	Tape, Attachment, Neonate	100/pkg
3137	Tape, Attachment, Infant	100/pkg
3138	Universal 'Y' Posey Wrap	10/pkg
3178	Pediatric Finger Sensor	each
3311	Cable, Oximetry, 1.5 m (5 feet)	each
3444	Comfort Clip® Finger Sensor, Oximetry	each
5093	$ETCO_2$ Calibration Gas, (10% CO_2, 21% O_2, bal N_2)	each
8030	Adapter, Airway, Elbow, 15ID/22OD x 15OD (mm)	10/pkg
8044	CO_2 Sample Line, 2.4 m (8 feet)	10/pkg

CAT. NO.	DESCRIPTION	QTY
8061	Calibration Gas Flow Regulator	each
8208	Gas Manifold Filters	10/pkg
8211	CO_2 Sample Line, 1.2 m (4 feet)	10/pkg
8214	Patient Attachment kit (1100, 8211, 8208)	10/pkg
8217	Capnocheck® Calibration Kit (5093, 8061, 8223, 8211)	each
8400	Capnograph/Oximetry w/ Battery and Charger	each
8403	Battery Eliminator, 105-125 V, 60 Hz	each
8404	Battery Charger	each
8406	Battery Eliminator, 208-252V, 50/60 Hz	each
8407	Battery Eliminator, 90-110V, 60 Hz	each
8408	Battery, 7.4 V Lithium-Ion Rechargeable	each
8409	Pole Mount Bracket	each
8411	Infrared Printer, Martel MCP8850B	each
8412	Protective Rubber Boot	each
8414	Carrying Case	each
8416	Infrared Printer Paper	4/box

** The BCI® 1302 and 3026 oximetry sensors should not be used on neonatal patients with the Capnograph monitor. Testing has not been conducted for the Capnograph for patients less than 30 days old. These sensors may, however, be used on older patients.*

Ordering Information

For ordering information, contact your local distributor or the Smiths Medical PM, Inc. customer service department.

Smiths Medical PM, Inc.
N7W22025 Johnson Drive
Waukesha, WI USA 53186-1856

Phone: (262) 542-3100
Toll-Free: (800) 558-2345
Fax: (262) 542-0718

e-mail address: info.pm@smiths-medical.com

Chapter 14: Specifications

Capnograph

Display:	LCD, with electroluminescent (EL) back light 160 X 160 pixels; 38.4 cm2, 62 x 62 mm
Measurement:	Non-Dispersive IR absorption
Calibration:	Manual 2 point.
Measurement Range:	0-10% CO_2 STPD (standard temperature and pressure dry)
Display Range:	0-100 mmHg; 0-13.3 kPa; 0-10% CO_2
Display Update Rate:	Waveform data updates at 24 Hz using a sliding erase bar to pro-vide sweep speeds. Numerical data and messages are updated at 1 Hz. $Sp0_2$ pulse strength bar and the breath indicator update at 60 Hz.
Accuracy:*	± 2mmHg or 4% of reading, whichever is greater
Stability:	≤ 0.3% (vol) CO_2 /24hrs
Rise Time:	325ms (average)
Delay Time:	2.140s (average)
System Response Time:	2.465s (average)
Time from power on to accurate readings:	3 minutes (typical)
N2O Compensation:	selectable 40% (default = OFF)
Averaging:	4 breath average
Flow Rate:	120 ± 20 ml/min

* Accuracy specification for respiration rates less than 50 breaths per minute. $ETCO_2$ specification for 51-80 breaths per minute is –10% of reading and for 81-150 breaths per minute is –20% of the reading.

Respiration Rate

Range:	0-150 breaths/min
Accuracy:	± 1 bpm
Averaging:	4 breath average
Display Update Rate:	1 Hz for Respiration value

SpO_2 (optional)

Range:	0-100% SpO_2 (functional)
Accuracy: [1]	± 2 at 70-100% SpO_2 ± 3 at 50-69% SpO_2
Averaging:	8 beats
Pulse Tone:	Pitch corresponds to SpO_2 value. Value adjustable or OFF.
Display Update Rate:	1Hz for SpO_2 value, 60Hz for waveform
Sensor:	Red 660nm, 2.0 mW Infrared 905 nm, 2.0 - 2.4 mW
Calibration:	Factory calibrated over 50% to 100% using human blood samples to functional saturation. Test methods available upon request. No in-service calibration required.

[1] Because pulse oximeter measurements are statistically distributed, only about two-thirds of pulse oximeter equipment can be expected to fall within the A_{RMS} of the value measured by the CO-oximeter. The 8400 Capnocheck® II has been validated in human desaturation studies on 10 adult volunteers that did not have health problems and were non-smokers. The study was conducted at oxygen concentrations evenly distributed over an SaO_2 range of 50-100%.

Peripheral Pulse Rate (optional)

Range:	30-254 bpm
Accuracy:	±2 bpm or 2%, whichever is greater, at 30 to 254 bpm
Averaging:	8 seconds
Display Update Rate:	1Hz

Pulse Strength (optional)

NOT proportional to pulse volume!

Range:	30-254 bpm, indicates logarithmic strength of patient's pulse
Display:	8 segment bargraph
Display Update Rate:	60Hz

Alarm Limits Ranges

$ETCO_2$

High:	0-100 mmHg (1 mmHg steps), and OFF 0-13.3 kPa (0.1 kPa steps), and OFF 0-10.0% CO_2 (0.1% steps), and OFF
Low:	0-100 mmHg (1 mmHg steps), and OFF
Factory Defaults:	High = 60 mmHg Low = 20 mmHg

Resp Rate

High:	5-150 bpm (1 bpm steps), and OFF
Low:	5-150 bpm (1 bpm steps), and OFF
Factory Defaults:	High = 35 bpm Low = 5 bpm

Inspired CO_2

High:	0-100 mmHg (1 mmHg steps), and OFF 0-13.3 kPa, 0.1 kPa steps, and OFF 0-10.0% CO_2, 0.1% steps, and OFF
Factory Default:	High = 8 mmHg

Pulse Rate

High:	30-254 bpm (1 bpm steps), and OFF
Low:	30-254 bpm (1 bpm steps), and OFF
Factory Defaults:	High = 150 bpm Low = 45 bpm

SpO_2

High:	50-100% (1% steps), and OFF
Low:	50-100% (1% steps), and OFF
Factory Defaults:	High = OFF Low = 85%

Volume: 45dBA - 85dBA (adjustable) at 1 meter distance

NOTE! User set alarm limits will be retained through power cycles.

Serial Output

Infrared Port compatible with MCP8850B Printer or similar device.

Data Format:	Non-standard format ~ 500 baud
Options:	Text only, no graphics. Patient data log or trend tables

Power

AC Power (Optional) See *Chapter 13: Supplies and Accessories*

Battery Charger:	MoliEnergy Agency Approvals pending
Battery:	LI+ (lithium-Ion), 7.4 VDC Replaceable internal rechargeable. Fully charged continuous use life of approximately 6 hours. Maximum full-capacity charging time is 2.5 hours
Battery Disposal:	The battery must be disposed of properly. For more information contact your local authorities.

Physical

Dimensions

Width:	111 mm (4.38 inches)
Height:	127 mm (5 inches)
Depth:	73.7 mm (2.9 inches)
Weight:	0.63 kg (22 ounces)

Environment

Temperature

Operation:	0 to 50° C (32 to 122° F)
Storage:	-40 to +75° C (-40 to +167° F)

Relative Humidity

Operation:	15 to 95% (non-condensing)
Storage:	10 to 95% (non-condensing)
EMC:	As per the most recent FDA guidelines for Respiratory and Oximetry devices, and EN60601-1-2.
Atmospheric Pressure:	525 mmHg (10,000 feet above sea level) to 795 mmHg (1250 feet below sea level)

Appendix A: Guidance and Manufacturer's Declaration

Guidance and Manufacturer's Declaration

The 8400 Capnocheck® II capnograph is intended for use in the electromagnetic environment specified in the tables within this appendix.

NOTE! The customer or user of the 8400 Capnocheck® II capnograph should ensure that it is used in such an environment.

Electromagnetic Emissions - Emissions Test

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
RF emissions CISPR 11	Group 1	The 8400 Capnocheck® II capnograph uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The 8400 Capnocheck® II capnograph is suitable for use in all establishments, including: • Domestic establishments. • Establishments directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	NA	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	NA	

Electromagnetic Emissions – Immunity

IMMUNITY		ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	**IEC 60601 TEST LEVEL**	Floors should be made of: • Wood • Concrete • Ceramic tile If floors are covered with synthetic material, the relative humidity should be at least 30%.
	• ± 6 kV contact • ± 8 kV air	
	COMPLIANCE LEVEL	
	• ± 6 kV contact • ± 8 kV air	

IMMUNITY		ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Electrical fast transient/burst IEC 61000-4-4	**IEC 60601 TEST LEVEL** • ±2 kV for power supply lines. • ±1 kV for input/ output lines. **COMPLIANCE LEVEL** • ±2 kV for power supply lines. • ±1 kV for input/ output lines.	A.C. Mains power voltage should be the typical quality of a: • Commercial environment. • Hospital environment.
Surge IEC 61000-4-5	**IEC 60601 TEST LEVEL** • ±1 kV differential mode • ±2 kV common mode **COMPLIANCE LEVEL** • ±1 kV differential mode • ±2 kV common mode • NA for battery operated version	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	**IEC 60601 TEST LEVEL** • <5% UT (>95% dip in UT) for 0.5 cycle. • <40% UT (>60% dip in UT) for 5 cycles. • <70% UT (>30% dip in UT) for 25 cycles. • <5% UT (>95% dip in UT) for 5 seconds. **COMPLIANCE LEVEL** • <5% U_T (>95% dip in U_T) for 0.5 cycle. • <40% U_T (>60% dip in U_T) for 5 cycles. Device restarts without operator interference once U_T is brought to 100% • <70% U_T (>30% dip in U_T). Voltage was dropped for extended period of time • <5% U_T (>95% dip in U_T) for 5 seconds. Device had to be manually turned on as allowed by clause 36.202.7a)2) of IEC 60601-1-2:2001	If the user of the 8400 Capnocheck® II capnograph requires continued operation during power mains interruptions, it is recommended that the 8400 Capnocheck® II capnograph be powered from an uninterruptible power supply or a battery.
Note: U_T is the A.C. mains voltage prior to application of the test level.		

IMMUNITY		ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Power frequency (50/60 Hz) IEC 61000-4-8	**IEC 60601 TEST LEVEL**	Power frequency magnetic fields should be the typical levels of a: • Commercial environment • Hospital environment
	3 A/m	
	COMPLIANCE LEVEL	
	3 A/m	
Conducted RF IEC 61000-4-6	**IEC 60601 TEST LEVEL**	**Recommended separation distance:** $d = 1.2\sqrt{P}$
	• 3 Vrms • 150 kHz to 80MHz	
	COMPLIANCE LEVEL	
	• 3 Vrms • 10 kHz to 100 MHz.	
Radiated RF IEC 61000-4-3	**IEC 60601 TEST LEVEL**	**Recommended separation distance:** $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.70\sqrt{P}$ 800 MHz to 2.5 GHz
	• 3 V/m • 80 MHz to 2.5 GHz	
	COMPLIANCE LEVEL	
	• 10 V/m • 80 MHz to 1 GHz [c]	

- *P* = Manufacturer's output power in watts (W).
- *d* = Recommended distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b].

CAUTION! Interference may occur in the vicinity of equipment marked with the following symbol:

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed RF transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 8400 Capnocheck® II capnograph is used exceeds the applicable RF transmitter compliance level above, the 8400 Capnocheck® II capnograph should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 8400 Capnocheck® II capnograph.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

[c] Some unknown effects could result from the device not being tested in the 1 GHz-2.5 GHz range, however the risk of failure is low. Designs with good fault monitoring and reporting and user documentation mitigate the risk of failure. No Smiths Medical PM legacy devices that have been tested have ever failed in this range. This statement was confirmed by a complaints review.

Recommended Separation Distances

The 8400 Capnocheck® II capnograph is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. The customer or the user of the 8400 Capnocheck® II capnograph can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 8400 Capnocheck® II capnograph as recommended below, according to the maximum output power of the communications equipment.

The recommended separation distances between portable and mobile RF communication equipment and the 8400 Capnocheck® II capnograph is:

RATED MAXIMUM OUTPUT POWER OF RF TRANSMITTER (WATTS)	SEPARATION DISTANCE ACCORDING TO THE FREQUENCY OF RF TRANSMITTER (METERS)		
	150 kHz to 80MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2.5 GHz $d = 0.70\sqrt{P}$
0.01	0.12	0.035	0.07
0.1	0.37	0.11	0.22
1	1.2	0.35	0.70
10	3.7	1.1	2.2
100	12	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARNING! The monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the monitor should be observed to verify normal operation in the configuration in which it will be used.

Appendix B: Revision History

REVISION	DATE
Rev. 11	May, 2008

CHANGES

- Changed IEC standard from 950 to 60950.
- Fixed header in Chapter 2 to match Chapter title.
- Changed voltage range for part number 8407 to read 90-110.
- Changed Chapter 4 title to Alarms.
- Deleted ERROR: Low CO2 Out of Range from the calibration messages.

REVISION	DATE
Rev. 10	November, 2007

CHANGES

- Added BCI lozenge and Smiths Medical logo to front cover. Deleted Smiths Medical logo from back cover.
- Updated Limited Warranty section to say two years instead of one year.
- Added Australian Representative to Warranty section and back cover.
- Updated symbol table in Chapter 1.
- Added WEEE Recycling instructions and Smiths URL to symbol table in Chapter 1.

REVISION	DATE
Rev. 9	July, 2007

CHANGES

- Removed 8405 from the accessories list.
- Updated warranty and service information.
- Updated email address.
- Updated warnings, cautions and notes. Changed some cautions and notes to warnings.
- Changed font to Myriad Pro.
- Updated company name and CR authorized rep.
- Added this revision history.
- Added new design frame, Smiths Medical logo and company address to covers.
- Added WEEE symbol and updated symbol table.
- Updated oximeter sensor table with correct kg for pediatric.
- Added photodynamic therapy warning to oximetry.
- Added Smiths design mark trademark and updated proprietary notice.
- Added caution about certain cleaning agents causing brittleness or plastic.
- Added warning about erroneous pulse oximetry readings under certain conditions.
- Added new Theory of Operation, 1606 simulator notes, and SpO2 averaging notes.
- Added Guidance and Manufacturer's Declaration to Appendix A.
- Added notes about retained alarm limits, awareness of which alarm limits are being set.
- Added desat study info and alarm volume to Specifications.

CE
0473

Authorized Representative (as defined by the Medical Device Directive):

Smiths Medical International, Ltd.
Colonial Way, Watford, Herts,
WD24 4LG, UK

Phone: (44) 1923 246434
Fax: (44) 1923 240273

Australian Representative:

Smiths Medical Australasia Pty. Ltd.
61 Brandl Street, Eight Mile Plains,
QLD 4113, Australia

Tel: +61 (0) 7 3340 1300

Manufactured By

Smiths Medical PM, Inc.
N7W22025 Johnson Drive
Waukesha, WI 53186-1856 USA